Initial REMS Approval 8/2010

Most Recent Modification June/2013

REVLIMID® (lenalidomide)

NDA 021880

Celgene Corporation
86 Morris Avenue
Summit, NJ 07901

Contact Information:

1-908-673-9000
www.celgene.com

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1. GOALS

The goals of the REVLIMID risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to REVLIMID.
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for REVLIMID.

2. REMS ELEMENTS

2.1. Elements to Assure Safe Use

2.1.1. Healthcare providers who prescribe REVLIMID are specially certified.

Celgene will ensure that healthcare providers who prescribe REVLIMID are specially certified in the REVLIMID REMS™ program.

To become certified, each prescriber must complete the Prescriber Enrollment Form and agree to do the following:

a. Provide patient counseling on the benefits and risks of REVLIMID therapy, including risks described in the BOXED WARNINGS.
b. Enroll each patient by completing and submitting to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email (customercare@celgene.com), fax (1-888-432-9325), or online (www.celgeneriskmanagement.com), a signed Patient-Physician Agreement Form (PPAF) identifying the patient's risk category (see PPAFs for all six risk categories) for each new patient. In signing the PPAF, each prescriber acknowledges that they understand that REVLIMID is available only through the REVLIMID REMS™ program, and that they must comply with program requirements.
c. Provide contraception and emergency contraception counseling with each new prescription prior to and during REVLIMID treatment.

d. Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions.
e. Report any pregnancies in female patients or female partners of male patients prescribed REVLIMID immediately to Celgene Drug Safety (or Celgene Customer Care Center, 1-888-423-5436).
f. Complete a prescriber survey (phone or online) for every patient (new and follow-up), obtain a unique prescription authorization number for each prescription written, and include this authorization number on the prescription. The authorization number can be obtained by contacting the Celgene Customer Care Center, using the automated IVR system, or via the www.CelgeneRiskMangement.com website.
    - For females of reproductive potential, authorization numbers are valid only for 7 days from date of last pregnancy test and 30 days from the date it is issued for all other patients.
g. Facilitate compliance with the mandatory REVLIMID REMS™ program patient survey by instructing patients to complete the mandatory surveys (phone or online) at program specified frequencies.
h. Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
i. Contact a REVLIMID REMS™ program pharmacy certified by the REVLIMID REMS™ program to fill the REVLIMID prescription.
j. Return all unused REVLIMID brought in by patients to Celgene Customer Care.
k. Re-enroll patients in the REVLIMID REMS™ program if REVLIMID is required and previous therapy with REVLIMID has been discontinued for 12 consecutive months.

Celgene will:

1. Ensure that the REVLIMID REMS™ program materials including prescriber enrollment are available on the CelgeneRiskManagement.com website or can be obtained by contacting Celgene Customer Care Center at 1-888-423-5436
2. Maintain a secure database of all REVLIMID REMS™ program certified prescribers.
3. Monitor to ensure that only REVLIMID REMS™ program certified prescribers are prescribing REVLIMID.
4. Monitor and ensure that patients have been assigned correctly to one of the following patient risk categories. Confirm risk category when completing the PPAFs during the patient enrollment process:
    a. **Adult female of reproductive potential:** all females who are menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal.
    b. **Female child of reproductive potential:** all females under 18 years who are menstruating.
    c. **Adult female NOT of reproductive potential:** females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy.
    d. **Female child NOT of reproductive potential:** all females under 18 years who are not menstruating.
    e. **Adult males 18 years or older**
    f. **Male child under 18 years**
5. Monitor certified prescriber compliance with the REVLIMID REMS™ program, including patient risk categorization and the appropriate corresponding counseling requirements, contraception requirements, pregnancy testing, and survey completion for all patients treated with REVLIMID.

6. Institute corrective action and prevent the certified prescriber from prescribing REVLIMID if the prescriber is found to be non-compliant with the REVLIMID REMS™ program.
7. Train REVLIMID REMS™ program certified prescribers in adverse experience reporting procedures, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to REVLIMID if a pregnancy occurs.
8. Ensure that once the prescriber submits the completed PPAF, the prescriber will receive a confirmation letter via fax or online to confirm the patient's enrollment and signify that the prescriber and patient surveys can be taken to receive an authorization number for the REVLIMID prescription (for all males, the PPAF is considered the initial survey). The authorization number is written on the REVLIMID prescription.
9. Ensure that, for subsequent prescriptions, the prescriber completes a telephone or online survey designed to look for signals of at-risk behavior (e.g., pending or outdated pregnancy test), report the patient's pregnancy test results, correct assignment of risk category, and confirm or re-enforce patient understanding of contraceptive requirements. The completion of the survey will allow the prescriber to obtain a new authorization number every time a prescription for REVLIMID is written.

The following materials are part of the REMS, and are appended:

- Prescriber Enrollment Form
- Patient Prescription Form
- Patient Prescription Form (Veterans Administration)
- Prescriber Guide to REVLIMID REMS™ Program
- REVLIMID REMS™ At-A-Glance
- Welcome Letter
- CelgeneRiskManagement.com website

2.1.2. REVLIMID will only be dispensed by pharmacies that are specially certified.

Celgene will ensure that REVLIMID is only dispensed from REVLIMID REMS™ program certified pharmacies. To become a certified pharmacy, the pharmacy must agree to do the following before filling a REVLIMID prescription:

a. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.
b. Dispense no more than a 4-week (28-day) supply, and require a new prescription from the patient prior to dispensing additional REVLIMID.
c. Dispense subsequent prescriptions only if there are 7 days or less remaining on an existing REVLIMID prescription.
d. Obtain a REVLIMID REMS™ confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. The REVLIMID REMS™ confirmation number may be obtained using the following procedure:

1. Enter the pharmacy identification number (NABP or DEA);

2. Enter the prescription authorization number written on the prescription;
3. Enter the number of capsules and milligram (mg) strength being dispensed;
4. Dispense or ship the prescribed REVLIMID within 24 hours of obtaining and recording the REVLIMID REMS™ confirmation number and confirmation date.

e. Dispense REVLIMID only after a REVLIMID REMS™ program confirmation number is obtained. If no confirmation is obtained, then no REVLIMID is dispensed. Contact the patient's physician and Celgene for further instruction.

f. Accept unused REVLIMID (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.

g. For each patient receiving treatment, retain a record of each REVLIMID prescription dispensed and the corresponding completed REVLIMID REMS™ Education and Counseling Checklist.

h. Complete the checklist that applies to the REVLIMID REMS™ program patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.

i. Provide counseling to patients and/or guardians of patients under 18 years of age receiving REVLIMID treatment.

   a. Counsel all patients and guardians of patients under 18 years of age on the following:

      1. The benefits and risks of REVLIMID therapy.
      2. Not sharing REVLIMID medication
      3. Not donating blood while taking REVLIMID, during dose interruptions, and for 4 weeks after stopping REVLIMID.
      4. Not to break, chew, or open REVLIMID capsules.
      5. Instructions on REVLIMID dose and administration.
      6. To read the REVLIMID REMS™ program education materials and encourage compliance with the requirements.

   b. In addition to above, counsel **Females of Reproductive Potential** on the following:

      1. The potential for embryo-fetal toxicity with exposure to REVLIMID.
      2. Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse.
      3. Continuing to use 2 forms of birth control if REVLIMID therapy is interrupted and for at least 4 weeks after therapy is discontinued.
      4. Obtaining a pregnancy test weekly during the first 4 weeks of REVLIMID use, then a repeat pregnancy test every 4 weeks in females with regular menstrual cycles, and every 2 weeks in females with irregular menstrual cycles.
      5. The need to stop taking REVLIMID and notify their REVLIMID prescriber immediately if they become pregnant or suspect they may be pregnant.

   c. In addition to items listed for all patients above, counsel **Males** receiving REVLIMID treatment about the potential for embryo-fetal toxicity with exposure to REVLIMID and the importance of using barrier contraception by wearing a latex or synthetic condom when engaging in sexual intercourse with a female of reproductive potential even if the male receiving REVLIMID has had a successful vasectomy.

      1. The need to not donate sperm while taking REVLIMID, during dose interruptions, and for 4 weeks after stopping REVLIMID.

d. Counsel the **Parent or legal guardian of Female Child NOT of reproductive potential** who is receiving REVLIMID treatment about the need to inform their REVLIMID prescriber when the child begins menses.

Before a certified pharmacy dispenses REVLIMID, Celgene will train the appropriate pharmacy staff:

1. About the REVLIMID REMS™ program
2. About the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to REVLIMID if a pregnancy occurs.

The following materials are part of the REMS, and are appended:

- Pharmacy Guide to REVLIMID REMS™ Program
- Education and Counseling Checklist for Pharmacies
- Celgene REMS Programs Pharmacy Training: REVLIMID REMS™
- Pharmacy Certification Quiz (the REVLIMID REMS™ Program)

2.1.3. Celgene will ensure that REVLIMID® will only be dispensed to patients enrolled in the REVLIMID REMS™ program with evidence or other documentation of safe-use conditions.

Celgene will ensure that all patients treated with REVLIMID are enrolled by a certified prescriber. The prescriber will enroll the patient by completing Patient-Physician Agreement Form and submitting the form via mail (86 Morris Avenue, Summit, NJ 07901), fax (1-888-432-9325), email (customercare@celgene.com) or online (www.celgeneriskmanagement.com) for each patient who receives REVLIMID. Each patient and/or guardian of patients under 18 years of age consents to participate in the program by:

a. acknowledging that he or she understands that:
   i. severe birth defects or death to an unborn baby may occur if a female becomes pregnant while she is receiving REVLIMID;
   ii. REVLIMID must not be shared with anyone, even someone with similar symptoms;
   iii. REVLIMID must be kept out of the reach of children and should NEVER be shared with females who are able to have children;
   iv. they cannot donate blood while receiving REVLIMID including during dose interruptions, and for 4 weeks after stopping REVLIMID;
   v. they might be asked to participate in the REVLIMID Pregnancy Exposure Registry; and
   vi. they may be contacted by Celgene about following the rules of the REMS.

b. In addition, each patient and/or guardian of patients under 18 years of age consents to participate in the program by:
   i. agreeing to return unused REVLIMID to Celgene or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them ;
   ii. agreeing to participate in a monthly (telephone or online) survey while on REVLIMID (with the exception of Adult Females Not of Reproductive Potential who are required to take a survey once every six months); and

iii. reviewing the REVLIMID REMS™ program educational materials and asking their prescriber any questions that have not been answered.

In addition, **Females and guardians of female children** must attest to their understanding of their/their child's reproductive potential, as categorized by the prescribing physician.

Females of Reproductive Potential and guardians of Female Children of Reproductive Potential will attest that they/their child:

a. is not currently pregnant, and will try to refrain from becoming pregnant while receiving REVLIMID therapy and for at least 4 weeks after completely stopping REVLIMID therapy;

b. must not take REVLIMID if pregnant, breastfeeding a baby, or not using birth control as defined in the REMS;

c. will, unless abstinent, use contraception as defined within the REMS: for at least 4 weeks before starting REVLIMID, while receiving REVLIMID, during dose interruptions, and for at least 4 weeks after stopping REVLIMID;

d. will have pregnancy testing done as ordered by the certified prescriber within 10 to 14 days and 24 hours prior to starting REVLIMID, every week for at least the first 4 weeks of REVLIMID therapy, and then every 4 weeks if the Female of Reproductive Potential has regular menstrual cycles, or every 2 weeks if the Female of Reproductive Potential has irregular menstrual cycles, while receiving REVLIMID;

e. will immediately stop taking REVLIMID and inform the certified prescriber if the patient becomes pregnant, misses a menstrual period, experiences unusual menstrual bleeding, stops using contraception, or thinks for any reason that she might be pregnant; if the prescriber is not available, the Female of Reproductive Potential or guardian of a Female Child of Reproductive Potential can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception.

Males or Guardians of males will attest that they/their child will:

a. never have unprotected sexual contact with a female who can become pregnant;

b. wear a latex or synthetic condom every time the male patient has sexual contact with a female who is or who can become pregnant; continue condom use with sexual contact while the male patient is receiving REVLIMID treatment, during dose interruptions, and for 4 weeks after the male patient stops taking REVLIMID, even if the patient has had a successful vasectomy; and

c. inform their certified prescriber if the male patient has unprotected sexual contact with a female who can become pregnant, or if they think for any reason that the male patient's sexual partner might be pregnant; the male patient or guardian of an underage male patient can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception;

d. not donate sperm while taking (including dose interruptions) and for 4 weeks after stopping REVLIMID

The following appended materials are part of the REMS:

- Patient-Physician Agreement Form for Adult Male

- Patient-Physician Agreement Form for Male Child
- Patient-Physician Agreement Form for Adult Female Who Can Not Get Pregnant
- Patient-Physician Agreement Form for Adult Female Who Can Get Pregnant
- Patient-Physician Agreement Form for Female Child Who Can Not Get Pregnant
- Patient-Physician Agreement Form for Female Child Who Can Get Pregnant
- Patient Guide to REVLIMID REMS™ Program
- Emergency Contraception Brochure
- Patient Survey Reminder Card
- REVLIMID RiskEvaluation andMitigation Strategy (REMS)™ Program Education and Safety Kit
- REVLIMID REMS™ Patient Resource Pack Envelope

2.1.4. Female patients or female partners of male patients receiving REVLIMID who report a pregnancy that occurred during REVLIMID therapy will be enrolled in the REVLIMID Pregnancy Exposure Registry.

Upon receiving a report of pregnancy from the REVLIMID REMS™ program, Celgene Pregnancy Prevention Plan programs in the rest of the world, clinical trials, or directly from a prescriber, a pharmacy, or a patient, Celgene will enroll the female patient or female partner of the male patient taking REVLIMID into the REVLIMID Pregnancy Exposure Registry. The objectives of the registry are to monitor pregnancy outcomes in female patients of reproductive potential and male patients' female partners who are exposed to REVLIMID and to understand why the REVLIMID REMS™ program was unsuccessful.

The following materials are part of the REMS and are appended:

1) REVLIMID Pregnancy Exposure Registry Protocol, including letter and questionnaires

2.2. Implementation System

The implementation system will include the following:

1) Celgene will maintain a secure database of all certified entities, including enrolled patients and certified prescribers and pharmacies to monitor and evaluate implementation of the elements provided for in Sections 2.1.1, 2.1.2, and 2.1.3.
2) Celgene will monitor pharmacy certification compliance and address deviations by monitoring real time dispensing activity and conducting pharmacy audits.
    a. The Celgene Customer Care Center will monitor the certified pharmacies in the manner described in the REMS supporting document to ensure only enrolled and authorized patients are receiving REVLIMID. If a certified pharmacy is found to be non-compliant with the REVLIMID REMS™ program, Celgene will institute corrective action and may de-activate pharmacies for which re-training has proven ineffective, removing them from the REVLIMID REMS™ program.
    b. Celgene will perform regular on-site audits of contract pharmacies participating in the REVLIMID REMS™ program. For pharmacies that have been in the program for more than two years, Celgene will perform a risk-based assessment to select which pharmacies will be audited. The REVLIMID REMS™ program compliance audits will be performed by internal auditors of Celgene and/or outside auditors contracted and trained by Celgene.

3) Celgene will monitor and ensure that the prescriptions are filled within the allowed timeframes.
4) Celgene Customer Care Center will address customer complaints received that are related to the REVLIMID REMS™ program and distribution and dispensing of REVLIMID.
5) Celgene will maintain a reporting and collection system for safety information that includes a process to monitor pregnancy testing results and pregnancy outcomes (should one occur) through the REVLIMID Pregnancy Exposure Registry and to understand why the REVLIMID REMS™ program was unsuccessful for the pregnancy case in question.
6) Based on monitoring and evaluation of these elements to assure safe use, Celgene will take reasonable steps to work to improve implementation of these elements as applicable.
7) Celgene will develop and follow written procedures related to the implementation of the REMS.

2.3. Timetable for Submission of Assessment Reports

Celgene will submit REMS assessments at six months and then annually following the initial approval date of the REMS (August 3, 2010). To facilitate inclusion for as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Celgene will submit each assessment so it will be received by the FDA on or before the due date.

REVLIMID® (lenalidomide) Patient Prescription Form

Today's Date_____ **Date Rx Needed**_____

Patient Last Name_____ Patient First Name_____

Phone Number (_____)_____

Shipping Address_____

City_____ State_____ Zip_____

Date of Birth_____ Patient ID#_____

Language Preference: ☐English ☐Spanish
☐Other_____

Best Time to Call Patient: ☐AM_____ ☐PM_____

Patient Diagnosis (ICD-9 Code)_____

Patient Allergies_____

Other Current Medications_____

Prescriber Name_____

State License Number_____

Prescriber Phone Number (___)_____Ext.____

Fax Number (___)_____

Prescriber Address_____

City_____ State____ Zip_____

Patient Type From PPAF (Check one)

☐Adult Female – NOT of Reproductive Potential

☐Adult Female – Reproductive Potential

☐Adult Male

☐Female Child – Not of Reproductive Potential

☐Female Child – Reproductive Potential

☐Male Child

PRESCRIPTION INSURANCE INFORMATION
(Fill out entirely and fax a copy of patient's insurance card, both sides)

Primary Insurance_____

Insured_____

Policy #_____

Group #_____

Phone #_____

Rx Drug Card #_____

Secondary Insurance_____

Insured_____

Policy #_____

Group #_____

Phone #_____

Rx Drug Card #_____

For further information on REVLIMID, please refer to the full Prescribing Information

TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING:

Recommended Starting Dose: See below for dosage

Myelodysplastic Syndromes: The recommended starting dose of REVLIMID is 10 mg/day with water. Dosing is continued or modified based upon clinical and laboratory findings.

Multiple Myeloma and Mantle Cell Lymphoma: The recommended starting dose of REVLIMID is 25 mg/day orally for Days 1 – 21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings

REVLIMID Dose	**Quantity**	**Directions**
☐ **2.5 mg**	_____	_____
☐ **5 mg**	_____	_____
☐ **10 mg**	_____	_____
☐ **15 mg**	_____	_____
☐ **20 mg**	_____	_____
☐ **25 mg**	_____	_____

☐**Dispense as Written** ☐**Substitution Permitted**

NO REFILLS ALLOWED (Maximum Quantity = 28 days)

Prescriber Signature_____ **Date**_____

Authorization #_____ **Date**_____
(To be filled in by healthcare provider)

Pharmacy Confirmation #_____ **Date**_____
(To be filled in by pharmacy)

How to Fill a REVLIMID® (lenalidomide) Prescription

1. Healthcare provider (HCP) instructs female patients to complete initial patient survey

2. HCP completes survey

3. HCP completes patient prescription form

4. HCP obtains REVLIMID REMS™ (formerly known as the RevAssist® program) authorization number

5. HCP provides authorization number on patient prescription form

6. **HCP faxes form, including prescription, to one of the Celgene Certified Pharmacy Network participants (see below)**

7. HCP advises patient that a representative from the certified pharmacy will contact them

8. Certified pharmacy conducts patient education

9. Certified pharmacy obtains confirmation number

10. Certified pharmacy ships REVLIMID to patient with MEDICATION GUIDE

Please see www.Celgene.com/PharmacyNetwork for the list of pharmacy participants

Information about REVLIMID and the REVLIMID REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at **www.CelgeneRiskManagement.com.**

REVLIMID® (lenalidomide)
Patient Prescription Form – Veterans Administration (VA) ONLY

Today's Date_____ **Date Rx Needed**_____

Patient Last Name_____ Patient First Name_____

Phone Number (_____)_____

Shipping Address_____

City_____ State_____ Zip_____

Date of Birth_____ Patient ID#_____

Language Preference: ☐English ☐Spanish

☐Other_____

Best Time to Call Patient: ☐AM_____ ☐PM_____

Patient Diagnosis (ICD-9 Code)_____

Patient Allergies_____

Other Current Medications_____

Prescriber Name_____

State License Number_____

Prescriber Phone Number (___)_____Ext.____

Fax Number (___)_____

Prescriber Address_____

City_____ State_____ Zip_____

Patient Type From PPAF (Check one)

☐Adult Female – NOT of Reproductive Potential

☐Adult Female – Reproductive Potential

☐Adult Male

☐Female Child – Not of Reproductive Potential

☐Female Child – Reproductive Potential

☐Male Child

A Pharmacy Information (Fill out entirely)

VA Name_____

Address_____

City_____ State_____ Zip____

VA Pharmacist Name_____

Phone #_____

Fax #_____

McKesson Specialty Distribution Account #

_____

Shipping Information

Check below for direct delivery to patient. If any information is omitted, product will be shipped to the VA Pharmacy.

☐ Patient

Name _____ Address _____

City_____ State_____ Zip____

Phone_____

For further information on REVLIMID, please refer to the full Prescribing Information

TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING:

Recommended Starting Dose: See below for dosage

Myelodysplastic Syndromes: The recommended starting dose of REVLIMID is 10 mg/day with water. Dosing is continued or modified based upon clinical and laboratory findings.

Multiple Myeloma and Mantle Cell Lymphoma: The recommended starting dose of REVLIMID is 25 mg/day orally for Days 1 – 21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings.

REVLIMID

Dose	Quantity	Directions
☐ **2.5 mg**		
☐ **5 mg**		
☐ **10 mg**		
☐ **15 mg**		
☐ **20 mg**		
☐ **25 mg**		

☐**Dispense as Written** ☐**Substitution Permitted**

NO REFILLS ALLOWED (Maximum Quantity = 28 days)

Prescriber Signature_____ **Date**_____

Authorization #_____ **Date**_____

(To be filled in by healthcare provider)

Pharmacy Confirmation #_____ **Date**_____

(To be filled in by pharmacy)

How to Fill a REVLIMID® (lenalidomide) Prescription in the Veterans Administration (VA)

1. Healthcare Provider (HCP) instructs female patients to complete initial patient survey

2. HCP completes survey

3. HCP completes patient prescription form (include cell number for patient if possible)

4. HCP obtains REVLIMID REMS™ (formerly known as the RevAssist® program) authorization number

5. HCP provides authorization number on patient prescription form

6. HCP sends prescription to the VA Pharmacy

The following information must be filled in:

- **Rx must include McKesson Specialty Distribution account number**
- **Rx must include VA address** (Name, Street, City, State, ZIP)
- **Rx must include VA Pharmacist contact information** (Name, Phone and Fax #)

7. VA Pharmacist faxes the form, including prescription, to:

The REVLIMID REMS™ certified Walgreens Specialty at 1-888-591-8482

8. HCP advises patient that a representative from REVLIMID REMS™ certified pharmacy will be in contact

9. The REVLIMID REMS™ certified Walgreens Specialty Pharmacist conducts patient education

10. The REVLIMID REMS™ certified Walgreens Specialty Pharmacist obtains confirmation number

11. The REVLIMID REMS™ certified Walgreens Specialty Pharmacist ships REVLIMID to the VA Pharmacy or directly to the patient with MEDICATION GUIDE

12. VA Pharmacist gives REVLIMID to VA patient with MEDICATION GUIDE

REVLIMID REMS™ Veterans Administration (VA) Pharmacy

Walgreens Specialty
Phone: 1-877-865-9396
Fax: 1-888-591-8482
Information about REVLIMID and the REVLIMID REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at **www.CelgeneRiskManagement.com**.

Prescriber Guide to
((REVLIMID REMS™ logo))
Risk Evaluation and Mitigation Strategy (REMS)™ Program

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID® (lenalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program).

This guide contains important information for prescribers about:

- The risks of REVLIMID, including a boxed warning for
  - Embryo-fetal toxicity
  - Hematologic toxicity
  - Deep vein thrombosis

- The REVLIMID REMS™ program
  - Prescriber Certification
  - Patient Enrollment
  - Contraceptive Requirements and Counseling for Patients
  - Initial and Subsequent Prescription Requirements

REVLIMID REMS™ Resources for Prescribers Include:

- Prescriber Guide to REVLIMID REMS™ Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for REVLIMID

Table of contents

About REVLIMID® (lenalidomide)

REVLIMID in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Risks of REVLIMID

REVLIMID has a Boxed Warning for embryo-fetal toxicity, hematologic toxicity, and deep venous thrombosis (DVT) and pulmonary embolism (PE).

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID if they take adequate precautions to avoid pregnancy.

REVLIMID is associated with significant neutropenia and thrombocytopenia in patients with del 5q MDS. Many patients taking REVLIMID may require dose interruption and/or reduction. Evaluate your del 5q MDS patients closely for cytopenias. Patients on REVLIMID should have their complete blood counts monitored weekly for the first 8 weeks of therapy, and at least monthly thereafter.

There is a significant risk of deep venous thrombosis and pulmonary embolism in patients with MM taking REVLIMID plus dexamethasone in combination. Patients and physicians should 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, or arm or leg swelling. It is not known if preventive anticoagulation or antiplatelet therapy prescribed in conjunction with REVLIMID may lessen the potential for thromboembolic events. The decision to take prophylactic measures should be done carefully after an assessment of an individual patient's underlying risk factors.

The REVLIMID REMS™ program

To avoid embryo-fetal exposure, REVLIMID® (lenalidomide) is only available under a restricted distribution program called "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™." Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID in the REVLIMID REMS™ program.
In order to receive REVLIMID, all patients must be enrolled in REVLIMID REMS™ and agree to comply with the requirements of the REVLIMID REMS™ program. Information about REVLIMID and the REVLIMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

Key points of the REVLIMID REMS™ program

Prescriber

- The prescriber enrolls and becomes certified with Celgene for the REVLIMID REMS™ program
- The prescriber counsels patient on benefits and risks of REVLIMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a REVLIMID® (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends REVLIMID prescription to certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for REVLIMID REMS™
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses REVLIMID to patient along with a Medication Guide

REVLIMID REMS™ patient enrollment

- Obtain, review, and complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**
- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with REVLIMID REMS™ program materials.

For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant

- Patient, parent/legal guardian, and/or authorized representative must read the REVLIMID® (lenalidomide) Patient-Physician Agreement Form in the language of their choice

Help Ensure Timely Processing of Each Prescription

Fill Out Form as Directed

- Write only in the designated areas on the REVLIMID® (lenalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an "X") to indicate understanding
- The form must be completed and signed by both prescriber and patient

Instructions for Female Patients

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

Instructions for Minors

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an "X") and agree to ensure compliance by signing and dating the form

Instructions for Incompetent Adult Patients

- For an incompetent adult patient, an authorized representative must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form

REVLIMID REMS™ patient enrollment (continued)

- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient's behalf
- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMS™ program and is authorized to consent to treatment with REVLIMID on behalf of the patient

Send in Completed Forms

- Send the completed REVLIMID® (lenalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once REVLIMID® (lenalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

Note: If therapy with REVLIMID is discontinued for 12 consecutive months, the patient must enroll again in the REVLIMID REMS™ program. Follow the above procedures to re-enroll the patient.

Initial prescription requirements

ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with REVLIMID® (lenalidomide)
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with REVLIMID
- Provide counseling not to share REVLIMID capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of REVLIMID, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the REVLIMID REMS™ Patient Resource Pack
- Patients should be instructed to not extensively handle or open REVLIMID capsules
- Instruct patients to return unused REVLIMID capsules for disposal to Celgene or to their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them

FEMALE PATIENTS

Determine if female patient is of reproductive potential

Two categories:
1. Females of Reproductive Potential • All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category **2. Females Not of Reproductive Potential** • Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

Initial prescription requirements (continued)

1. Females of Reproductive Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for REVLIMID® (lenalidomide) and again within 24 hours prior to writing an initial prescription for REVLIMID even if continuous abstinence is the chosen method of birth control
    - The pregnancy test must be sensitive to at least 50 mIU/mL
    - Pregnancy testing should occur weekly during the first 4 weeks of use
    - Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
    - If a patient misses her period or if there is any abnormality in menstrual bleeding, REVLIMID should be discontinued immediately. Obtain a pregnancy test and counsel the patient

- **If pregnancy does occur during treatment, REVLIMID must be immediately discontinued.** Any suspected embryo-fetal exposure to REVLIMID must be reported immediately to the FDA via the MedWatch number at **1-800-332-1088** and also to the Celgene Customer Care Center at **1-888-423-5436**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with REVLIMID

Initial prescription requirements (continued)

Patient Counseling on Contraception Requirements

Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before REVLIMID® (lenalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control to Use Together

Highly effective birth control methods		Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	+	Male latex or synthetic condom Diaphragm Cervical cap

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

- **Unacceptable forms of contraception:**
  - Progesterone-only "mini-pills"
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield*

- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

* A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

Initial prescription requirements (continued)

2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy
- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before REVLIMID® (lenalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking REVLIMD therapy is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of REVLIMID

Del 5q MDS PATIENTS

- Evaluate your del 5q MDS patients closely for cytopenias. Obtain a weekly CBC for the first 8 weeks of treatment, and at least monthly thereafter

Initial mandatory confidential survey

Females

- Instruct the female patient to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements.

Males

- Males do not need to take the initial survey

Prescribers

Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:

  - Prescriber's identification number
  - Patient's identification number
  - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
  - Average daily dose
  - Total number of days supply (cannot exceed 28 days)

- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

ADDITIONAL INFORMATION FOR THE PRESCRIBER

- Healthcare provider must send the prescription to a REVLIMID REMS™ certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

Subsequent prescription requirements

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for REVLIMID® (lenalidomide) is written.
No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

FEMALE PATIENTS

- Provide counseling as outlined in the "FEMALE PATIENTS" section on pages 7-10
- Follow pregnancy test requirements as outlined in the "Pregnancy test requirements" section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
    - Before prescription is obtained
    - Monthly
        - Adult females of reproductive potential
        - All female children
    - Every 6 months
        - Adult females not of reproductive potential

MALE PATIENTS

- Provide patient counseling as outlined in the "MALE PATIENTS" section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
    - Males do not complete an initial survey

Del 5q MDS PATIENTS

- Evaluate your del 5q MDS patients closely for cytopenias. Obtain a weekly CBC for the first 8 weeks of treatment and at least monthly thereafter

After the last dose of REVLIMID® (lenalidomide)

After patients have stopped taking REVLIMID, they must do the following:

ALL PATIENTS

- Must not share REVLIMID capsules—especially with females of reproductive potential
- Must return any unused REVLIMID capsules for disposal to Celgene or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them
- Must not donate blood for 4 weeks after stopping REVLIMID

FEMALE PATIENTS

- Must not get pregnant for at least 4 weeks after stopping REVLIMID by using the appropriate contraceptives each time engaging in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping REVLIMID
- Must not donate sperm for 4 weeks after stopping REVLIMID

Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

- Materials are available in 16 languages and include:
  - REVLIMID® (lenalidomide) Patient-Physician Agreement Forms
  - Patient Guide to REVLIMID REMS™ Program
  - Mandatory confidential survey forms

Available languages:

Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- REVLIMID® (lenalidomide) Patient-Physician Agreement Forms, Patient Guide to REVLIMID REMS™ Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

Name
Identification Number
Full Address
Fax Number

Patient's:

Name
Full Address
Phone Number
Date of Birth
Identification Number
Diagnosis (most recent version of ICD code)

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of REVLIMID® (lenalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online: **https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

[Back Cover]

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((REVLIMID REMS™ logo)) ((REVLIMID logo))

((REVLIMID REMS™ logo)

At-A-Glance

Important information about REVLIMID® (lenalidomide) and the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program

- REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™"(formerly known as the RevAssist ® program)
- Only prescribers and pharmacies certified by the REVLIMID REMS™ program can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMS™ program
- Information about REVLIMID and the REVLIMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) (REVLIMID REMS™ logo)) ((REVLIMID logo))

Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for REVLIMID® (lenalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open REVLIMID capsules.
3. Obtain, review, and complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
   - **Males (adults and children)**
   - **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
   - **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
4. Send the completed and signed REVLIMID® (lenalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
   - Males do not need to complete the initial survey
6. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
   - You will need to enter the following information:
     - Prescriber's identification number
     - Patient's identification number
     - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
     - Average daily dose
     - Total number of days supplied (cannot exceed 28 days)
7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
8. Send the prescription to a certified pharmacy.

Subsequent prescriptions (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open REVLIMID capsules.
3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
   - Monthly:
     - **Males (adults and children)**
     - **Females of reproductive potential (adults and children)**
     - **Female children not of reproductive potential**
   - Every 6 months:
     - **Adult females not of reproductive potential**
4. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.
   - You will need to enter the following information:
     - Prescriber's identification number
     - Patient's identification number
     - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
     - Average daily dose
     - Total number of days supplied (cannot exceed 28 days)
5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
6. Send the prescription to a certified pharmacy.

((REVLIMID REMS™ logo)) Prescriber Enrollment Form

All prescribers must be certified to prescribe REVLIMID® (lenalidomide). To become certified the prescriber must:

1. **Complete the Prescriber Enrollment Form which is required for REVLIMID REMS™ (formerly known as the RevAssist® program) certification.**
2. **Agree to steps on the following page that must be followed with every patient.**

To submit this form electronically, please go to www.CelgeneRiskManagement.com.

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy.

Please review the steps on the following page that must be followed with every patient.

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.
((REVLIMID logo))

REVLIMID REMS™ Prescriber Enrollment Form

When prescribing REVLIMID® (lenalidomide), I agree to:

- Provide patient counseling on the benefits and risks of REVLIMID therapy, including Boxed Warnings
- Submit a completed REVLIMID® (lenalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during REVLIMID treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed REVLIMID immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a REVLIMID REMS™ certified pharmacy to fill the prescription
- Return to Celgene all REVLIMID capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all REVLIMID capsules to Celgene Corporation or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them
- Re-enroll patients in the REVLIMID REMS™ program if REVLIMID is required and previous therapy with REVLIMID has been discontinued for 12 consecutive months

Please fill out the spaces below completely.

Prescriber Name _____

Degree: MD/DO/PA/NP/Fellow/Medical Resident

Specialty _____

Prescriber Identification Number _____

Please indicate which office(s) will receive REVLIMID REMS™ materials and updates:

☐ Primary Office Name_____

Attention _____

Address_____

City_____ State _____ZIP Code _____

Phone _____Ext._____ Fax_____

Email Address_____

☐ Secondary Office Name_____

Attention _____

Address_____

City_____ State _____ZIP Code _____

Phone _____Ext._____ Fax _____

Email Address_____

I understand that if I fail to comply with all requirements of the REVLIMID REMS™ program, my prescriptions for REVLIMID® (lenalidomide) will not be honored at certified pharmacies.

Prescriber Signature _____Date _____

Return this form to the Celgene Customer Care Center via fax or mail.

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: **1-888-423-5436**

Fax: **1-888-432-9325**

www.CelgeneRiskManagement.com

(Celgene logo)) ((REVLIMID REMS™ logo)) ((REVLIMID logo))

REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for you. REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ (formerly known as the RevAssist® program). Before taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMS™ program.
If you are pregnant or become pregnant while taking REVLIMID, it is important for you to know that your unborn baby can have severe birth defects or even die.
REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.
REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before *starting your treatment with REVLIMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the REVLIMID REMS™ materials contained in the **Patient Resource Pack.**
3. Keep a copy of this form for your records.

Authorized Representatives:
If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMS™ program and is authorized to consent to treatment with REVLIMID on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436.**

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ❒ REVLIMID can cause severe birth defects or death to my unborn baby if I am pregnant or become pregnant during treatment
- ❒ I am not pregnant now and will not get pregnant while being treated with REVLIMID
- ❒ It is possible for me to get pregnant if:
  - I am having my period (am menstruating), or
  - My period has stopped because of my treatment
  - And I have sex with a male
- ❒ Not having sex is the only birth control method that is 100% effective
- ❒ I am not breastfeeding now and will not breastfeed while being treated with REVLIMID
- ❒ My REVLIMID prescription is **only** for me and is not to be shared with others
- ❒ I have read and understood the REVLIMID Patient Guide to REVLIMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause
- ❒ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ❒ I may be contacted by Celgene to assist with the REVLIMID REMS™ program
- ❒ I will NOT donate blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

BAR CODE HERE

REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

❒ I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male unless otherwise recommended by my doctor. My doctor may recommend that I use **at the same time** 2 different birth control methods **every time** I have sex with a male if I cannot use a hormonal or intrauterine device (IUD) method

Highly effective birth control methods		Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	+	Male latex or synthetic condom Diaphragm Cervical cap

❒ I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male:

- Starting at least 4 weeks before taking REVLIMID
- While taking REVLIMID
- During breaks (dose interruptions)
- For at least 4 weeks after stopping REVLIMID

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

- ❒ I will have pregnancy tests—performed by my healthcare provider—according to the schedule listed below:
  - 10 to 14 days before receiving my first prescription for REVLIMID, and again 24 hours before receiving my first prescription for REVLIMID
  - Every week during the first 4 weeks of my treatment with REVLIMID
  - Every 4 weeks during the rest of my treatment if I have a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if I have an irregular menstrual cycle
- ❒ I will have these pregnancy tests even if I do not get my period because of my treatment
- ❒ I will need to take another pregnancy test performed by my healthcare provider if my medication is not dispensed within 7 days of taking my pregnancy test
- ❒ I will stop taking REVLIMID and call my doctor right away if I:
  - Become pregnant while taking REVLIMID, or
  - Miss my period or have unusual menstrual bleeding, or
  - Stop using birth control, or
  - Think—**for any reason**—that I am pregnant or may be pregnant
- ❒ If I become pregnant or think I may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my doctor is not available
- ❒ I will complete the mandatory confidential monthly survey while taking REVLIMID
- ❒ I will keep my REVLIMID prescription out of the reach of children
- ❒ I will return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused REVLIMID capsules can also be returned to my REVLIMID prescriber or to the pharmacy that dispensed the REVLIMID to me

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Section 2. Authorization

I understand and confirm that:

- ❒ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of REVLIMID
  - Evaluate the effectiveness of the REVLIMID REMS™ program
  - Use in any other manner as required or permitted by law
  - Provide me with information about REVLIMID or my condition
- ❒ This authorization will remain in effect for 12 months after I stop REVLIMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the REVLIMID REMS™ program
- ❒ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ❒ I may refuse to sign this authorization, which means that I do not want to participate in the REVLIMID REMS™ program. I understand that by refusing to participate in the REVLIMID REMS™ program, I will not be able to receive REVLIMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ❒ Upon signing this form, **I authorize my healthcare provider to begin my treatment with REVLIMID**

Celgene RevlimidREMS™ Revlimid® (lenalidomide) capsules

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the REVLIMID REMS™ program, I will not be able to receive REVLIMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with REVLIMID (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMS™ program.

<table>
<tr><th>Patient</th><th>Prescriber</th></tr>
<tr><td>Name</td><td>Name</td></tr>
<tr><td>Identification Number</td><td>Identification Number</td></tr>
<tr><td>Address</td><td>Address</td></tr>
<tr><td>Telephone Number</td><td>Telephone Number</td></tr>
<tr><td>Date of Birth | Sex</td><td>Fax Number</td></tr>
<tr><td>Risk Category
Menstruating:
Surgical Menopause:
Natural Menopause (24 months):</td><td rowspan="2"></td></tr>
<tr><td>Diagnosis</td></tr>
<tr><td>Patient or Authorized Representative's Signature:
Signature Date:</td><td>Prescriber's Signature :
Signature Date:</td></tr>
</table>

Prescriber, please fax all pages of the completed form to **1-888-432-9325.**

Give a copy of the form to the patient.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for you. REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ (formerly known as the RevAssist® program). Before taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMS™ program.

Any unborn baby of a female taking REVLIMID can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the REVLIMID Medication Guide

INSTRUCTIONS

Before *starting your treatment with REVLIMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the REVLIMID REMS™ materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMS™ program and is authorized to consent to treatment with REVLIMID on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ❒ REVLIMID can cause severe birth defects or death to unborn babies of females taking REVLIMID
- ❒ I am not pregnant
- ❒ I am not able to get pregnant because:
  - I have had both of my ovaries and/or my uterus removed, or
  - I have been in menopause for at least 2 years
- ❒ My REVLIMID prescription is **only** for me and is not to be shared with others
- ❒ I have read and understood the REVLIMID Patient Guide to the REVLIMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause
- ❒ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ❒ I may be contacted by Celgene to assist with the REVLIMID REMS™ program

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

I will:

- ❒ I will complete the mandatory confidential survey every 6 months while taking REVLIMID
- ❒ I will keep my REVLIMID prescription out of the reach of children
- ❒ I will return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**.
  Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused REVLIMID capsules can also be returned to my REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to me

I will not:

- ❒ I will **not** share my REVLIMID capsules with anyone even if they have symptoms like mine
- ❒ I will **not** donate blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Section 2. Authorization

I understand and confirm that:

- ❒ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
  - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
  - Analyze data for internal business purposes on the use of REVLIMID
  - Evaluate the effectiveness of the REVLIMID REMS™ program
  - Use in any other manner as required or permitted by law
  - Provide me with information about REVLIMID or my condition
- ❒ This authorization will remain in effect for 12 months after I stop REVLIMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the REVLIMID REMS™ program
- ❒ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ❒ I may refuse to sign this authorization, which means that I do not want to participate in the REVLIMID REMS™ program. I understand that by refusing to participate in the REVLIMID REMS™ program, I will not be able to receive REVLIMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ❒ Upon signing this form, **I authorize my healthcare provider to begin my treatment with REVLIMID**

Celgene RevlimidREMS™ Revlimid® (lenalidomide) capsules

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the REVLIMID REMS™ program, I will not be able to receive REVLIMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with REVLIMID and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMS™ program.

<table>
<tr><th colspan="2">Patient</th><th>Prescriber</th></tr>
<tr><td colspan="2">Name</td><td>Name</td></tr>
<tr><td colspan="2">Identification Number</td><td>Identification Number</td></tr>
<tr><td colspan="2">Address</td><td>Address</td></tr>
<tr><td colspan="2">Telephone Number</td><td>Telephone Number</td></tr>
<tr><td>Date of Birth</td><td>Sex</td><td>Fax Number</td></tr>
<tr><td colspan="2">Risk Category
Menstruating:
Surgical Menopause:
Natural Menopause (24 months):</td><td rowspan="2"></td></tr>
<tr><td colspan="2">Diagnosis</td></tr>
<tr><td colspan="2">Patient or Authorized Representative's Signature:

Signature Date:</td><td>Prescriber's Signature :

Signature Date:</td></tr>
</table>

Prescriber, please fax all pages of the completed form to **1-888-432-9325.**

Give a copy of the form to the patient.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for your child.* REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ (formerly known as the RevAssist® program). Before taking REVLIMID, patients must read and agree to all of the instructions in the REVLIMID REMS™ program.
If your child is pregnant or becomes pregnant while taking REVLIMID, it is important to know that the unborn baby can have severe birth defects or even die.
REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.
REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

***Before** your child starts treatment with REVLIMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.

2. Read the REVLIMID REMS™ materials contained in the **Patient Resource Pack**.

3. Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ❒ REVLIMID can cause severe birth defects or death to the unborn baby if my child is pregnant or becomes pregnant during treatment
- ❒ My child is not pregnant now and will not get pregnant while being treated with REVLIMID
- ❒ It is possible for my child to get pregnant if:
  - She has her period (is menstruating) or has shown any sign of puberty, or
  - Her period has stopped because of treatment
  - And she has sex with a male
- ❒ Not having sex is the only birth control method that is 100% effective
- ❒ My child is not breastfeeding now and will not breastfeed while being treated with REVLIMID
- ❒ My child's REVLIMID prescription is **only** for her and is not to be shared with others
- ❒ We have read and understood the REVLIMID Patient Guide to the REVLIMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause
- ❒ My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- ❒ We may be contacted by Celgene to assist with the REVLIMID REMS™ program
- ❒ My child will NOT donate blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

I will tell my child that:

❒ She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male unless otherwise recommended by her doctor. Her doctor may recommend that she use **at the same time** 2 different birth control methods **every time** she has sex with a male if she cannot use a hormonal or intrauterine device (IUD) method

Unless she chooses not to have sexual intercourse with a male at any time (abstinence), she must always use acceptable birth control

Highly effective birth control methods		Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	+	Male latex or synthetic condom Diaphragm Cervical cap

❒ She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male:

- Starting at least 4 weeks before taking REVLIMID
- While taking REVLIMID
- During breaks (dose interruptions)
- For at least 4 weeks after stopping REVLIMID

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

- ❒ She must have pregnancy tests—performed by her healthcare provider—according to the schedule listed below:
  - 10 to 14 days before receiving her first prescription for REVLIMID, and again 24 hours before receiving her first prescription for REVLIMID
  - Every week during the first 4 weeks of her treatment with REVLIMID
  - Every 4 weeks during the rest of her treatment if she has a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if she has an irregular menstrual cycle
- ❒ She must have these pregnancy tests even if she does not get her period because of her treatment
- ❒ She must take another pregnancy test performed by her healthcare provider if her medication is not dispensed within 7 days of taking her pregnancy test
- ❒ She must stop taking REVLIMID and I will call her doctor right away if she:
  - Becomes pregnant while taking REVLIMID, or
  - Misses her period or has unusual menstrual bleeding, or
  - Stops using birth control, or
  - Thinks—**for any reason**—that she is pregnant or may be pregnant
- ❒ If she becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my child's doctor is not available
- ❒ We will complete the mandatory confidential monthly survey while she is taking REVLIMID
- ❒ We will keep her REVLIMID prescription out of the reach of other children
- ❒ We will return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused REVLIMID capsules can also be returned to my child's REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to my child

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Section 2. Authorization

I understand and confirm that:

❒ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:

- Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
- Analyze data for internal business purposes on the use of REVLIMID
- Evaluate the effectiveness of the REVLIMID REMS™ program
- Use in any other manner as required or permitted by law
- Provide me and my child with information about REVLIMID or my child's condition

❒ This authorization will remain in effect for 12 months after my child stops REVLIMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the REVLIMID REMS™ program

❒ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party

❒ I may refuse to sign this authorization, which means that I do not want my child to participate in the REVLIMID REMS™ program. I understand that by refusing to have my child participate in the REVLIMID REMS™ program, she will not be able to receive REVLIMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition

❒ Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with REVLIMID**

Celgene RevlimidREMS™ Revlimid® (lenalidomide) capsules

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the REVLIMID REMS™ program, she will not be able to receive REVLIMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with REVLIMID (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMS™ program.

Patient		Prescriber
Name		*Name*
Identification Number		*Identification Number*
Address		*Address*
Telephone Number		*Telephone Number*
Date of Birth	*Sex*	*Fax Number*
Risk Category Menstruating: Surgical Menopause: Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature: *Signature Date:*		*Prescriber's Signature :* *Signature Date:*

Prescriber, please fax all pages of the completed form to **1-888-432-9325.**
Give a copy of the form to the parent/guardian.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for your child.* REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ (formerly known as the RevAssist® program). Before taking REVLIMID, patients must read and agree to all of the instructions in the REVLIMID REMS™ program.
Any unborn baby of a girl taking REVLIMID can have severe birth defects or even die.
REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.
REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).
For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before *your child starts treatment with REVLIMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 5.

2. Read the REVLIMID REMS™ materials contained in the **Patient Resource Pack**.

3. Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

☐ REVLIMID can cause severe birth defects or death to unborn babies of females taking REVLIMID

☐ My child is not pregnant

☐ My child is not able to get pregnant because she has not yet started her period (is not menstruating)

☐ My child's REVLIMID prescription is **only** for her and is not to be shared with others

☐ We have read and understood the REVLIMID Patient Guide to the REVLIMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause

☐ My child's healthcare provider has reviewed this information with us and answered any questions we have asked

☐ We may be contacted by Celgene to assist with the REVLIMID REMS™ program

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

I will tell my child that:

☐ We will complete the mandatory confidential monthly survey while my child is taking REVLIMID

☐ We will keep my child's REVLIMID prescription out of the reach of other children

☐ We will return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused REVLIMID capsules can also be returned to my child's REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to my child

☐ She must **not** share REVLIMID capsules with anyone even if they have symptoms like hers

☐ She must **not** donate blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Section 2. Authorization

I understand and confirm that:

☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:

- Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
- Analyze data for internal business purposes on the use of REVLIMID
- Evaluate the effectiveness of the REVLIMID REMS™ program
- Use in any other manner as required or permitted by law
- Provide me and my child with information about REVLIMID or my child's condition

☐ This authorization will remain in effect for 12 months after my child stops REVLIMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the REVLIMID REMS™ program

☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party

☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the REVLIMID REMS™ program. I understand that by refusing to have my child participate in the REVLIMID REMS™ program, she will not be able to receive REVLIMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition

☐ Upon signing this form**, I authorize my child's healthcare provider to begin my child's treatment with REVLIMID**

Celgene RevlimidREMS™ Revlimid® (lenalidomide) capsules

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the REVLIMID REMS™ program, she will not be able to receive REVLIMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with REVLIMID and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMS™ program.

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<tr><td>Name</td><td>Name</td></tr>
<tr><td>Identification Number</td><td>Identification Number</td></tr>
<tr><td>Address</td><td>Address</td></tr>
<tr><td>Telephone Number</td><td>Telephone Number</td></tr>
<tr><td>Date of Birth | Sex</td><td>Fax Number</td></tr>
<tr><td>Risk Category
Menstruating:
Surgical Menopause:
Natural Menopause (24 months):</td><td rowspan="2"></td></tr>
<tr><td>Diagnosis</td></tr>
<tr><td>Patient or Authorized Representative's Signature:

Signature Date:</td><td>Prescriber's Signature :

Signature Date:</td></tr>
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Prescriber, please fax all pages of the completed form to **1-888-432-9325.**
Give a copy of the form to the parent/guardian.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Male

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for you. REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ (formerly known as the RevAssist® program). Before taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMS™ program.

If a female you have sex with is pregnant or becomes pregnant by you while you are taking REVLIMID, it is important for you to know that your unborn baby can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before *starting your treatment with REVLIMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.

2. Read the REVLIMID REMS™ materials contained in the **Patient Resource Pack**.

3. Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMS™ program and is authorized to consent to treatment with REVLIMID on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436.**

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Male

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ❒ REVLIMID can cause severe birth defects or death to my unborn baby if I have sex with a female who is pregnant or who is able to get pregnant during my treatment
- ❒ My semen may contain REVLIMID even after I stop treatment. I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant while taking REVLIMID (including dose interruptions), and for 4 weeks after stopping REVLIMID
- ❒ Not having sex is the only birth control method that is 100% effective
- ❒ My REVLIMID prescription is **only** for me and is not to be shared with others
- ❒ I have read and understood the REVLIMID Patient Guide to the REVLIMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause
- ❒ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ❒ I may be contacted by Celgene to assist with the REVLIMID REMS™ program

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Male

- ❒ I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- ❒ I will use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant:
  - While taking REVLIMID
  - During breaks (dose interruptions)
  - For 4 weeks after stopping REVLIMID
- ❒ I will call my doctor right away if I:
  - Have unprotected sex with a female who is pregnant or who is able to get pregnant
  - Think—**for any reason**—that my sexual partner is pregnant or may be pregnant
- ❒ If my partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my doctor is not available
- ❒ I will complete the mandatory confidential monthly survey while taking REVLIMID
- ❒ I will keep my REVLIMID prescription out of the reach of children
- ❒ I will return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused REVLIMID capsules can also be returned to my REVLIMID prescriber, or to the pharmacy who dispensed the REVLIMID to me

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Male

❒ I will **not** share my REVLIMID capsules with anyone even if they have symptoms like mine

❒ I will **not** donate blood or sperm while taking REVLIMID during breaks (dose interruptions) and for 4 weeks after stopping REVLIMID

Section 2. Authorization

I understand and confirm that:

❒ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:

- Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
- Analyze data for internal business purposes on the use of REVLIMID
- Evaluate the effectiveness of the REVLIMID REMS™ program
- Use in any other manner as required or permitted by law
- Provide me with information about REVLIMID or my condition

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Male

- ❒ This authorization will remain in effect for 12 months after I stop REVLIMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the REVLIMID REMS™ program
- ❒ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ❒ I may refuse to sign this authorization, which means that I do not want to participate in the REVLIMID REMS™ program. I understand that by refusing to participate in the REVLIMID REMS™ program, I will not be able to receive REVLIMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ❒ Upon signing this form, **I authorize my healthcare provider to begin my treatment with REVLIMID**

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Male

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the REVLIMID REMS™ program, I will not be able to receive REVLIMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if he has any questions regarding his treatment with REVLIMID (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMS™ program.

Patient	Prescriber
Name	*Name*
Identification Number	*Identification Number*
Address	*Address*
Telephone Number	*Telephone Number*
Date of Birth	*Fax Number*
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	*Prescriber's Signature :*
Signature Date:	*Signature Date:*

Prescriber, please fax all pages of the completed form to **1-888-432-9325.**

Give a copy of the form to the patient.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Male Child

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for your child.* REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ (formerly known as the RevAssist® program). Before taking REVLIMID, patients must read and agree to all of the instructions in the REVLIMID REMS™ program.

If a female your child has sex with is pregnant or becomes pregnant by your child while he is taking REVLIMID, it is important to know that the unborn baby can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before *your child starts treatment with REVLIMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 6.

2. Read the REVLIMID REMS™ materials contained in the **Patient Resource Pack**.

3. Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436.**

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Male Child

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ❒ REVLIMID can cause severe birth defects or death to the unborn baby if my child has sex with a female who is pregnant or who is able to get pregnant during his treatment
- ❒ My child's semen may contain REVLIMID even after he stops treatment. He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant while taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID
- ❒ Not having sex is the only birth control method that is 100% effective
- ❒ My child's REVLIMID prescription is **only** for him and is not to be shared with others
- ❒ We have read and understood the REVLIMID Patient Guide to the REVLIMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause
- ❒ My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- ❒ We may be contacted by Celgene to assist with the REVLIMID REMS™ program

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Male Child

I will tell my child that:

- ❒ He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant, even if he has had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- ❒ He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant:
  - While taking REVLIMID
  - During breaks (dose interruptions)
  - For 4 weeks after stopping REVLIMID
- ❒ I will call his doctor right away if he:
  - Has unprotected sex with a female who is pregnant or who is able to get pregnant
  - Thinks—**for any reason**—that his sexual partner is pregnant or may be pregnant
- ❒ If my child's partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my child's doctor is not available
- ❒ We will complete the mandatory confidential monthly survey while my child is taking REVLIMID
- ❒ We will keep his REVLIMID prescription out of the reach of other children
- ❒ We will return any unused REVLIMID capsules to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give us a refund for the capsules my child did not take. Unused REVLIMID capsules can also be returned to my child's REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to my child

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Male Child

❒ He must **not** share his REVLIMID capsules with anyone even if they have symptoms like his
❒ He must **not** donate blood or sperm while taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID

Section 2. Authorization

I understand and confirm that:

❒ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:

- Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support®, and other companies
- Analyze data for internal business purposes on the use of REVLIMID
- Evaluate the effectiveness of the REVLIMID REMS™ program
- Use in any other manner as required or permitted by law
- Provide me and my child with information about REVLIMID or my child's condition

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Male Child

- ❒ This authorization will remain in effect for 12 months after my child stops REVLIMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the REVLIMID REMS™ program
- ❒ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ❒ I may refuse to sign this authorization, which means that I do not want my child to participate in the REVLIMID REMS™ program. I understand that by refusing to have my child participate in the REVLIMID REMS™ program, he will not be able to receive REVLIMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ❒ Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with REVLIMID**

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REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Male Child

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the REVLIMID REMS™ program, he will not be able to receive REVLIMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and his parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and his parent/guardian if they have any questions regarding the child's treatment with REVLIMID (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMS™ program.

Patient	Prescriber
Name	*Name*
Identification Number	*Identification Number*
Address	*Address*
Telephone Number	*Telephone Number*
Date of Birth	*Fax Number*
Sex	
Diagnosis	
Patient or Authorized Representative's Signature: *Signature Date:*	*Prescriber's Signature :* *Signature Date:*

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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[Housing Unit Cover Front Flap]

((REVLIMID REMS™ logo))

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety kit

[Housing Unit Cover]

Risks of REVLIMID® (lenalidomide)

- REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or embryo-fetal death. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

REVLIMID in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1—risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

((REVLIMID logo))

[Housing Unit Spine]

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety kit

[Housing Unit Back Cover]
((REVLIMID REMS™ logo))

Prescriber quick reference guide

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes REVLIMID® (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
   - Visiting **www.CelgeneRiskManagement.com**, or
   - Calling Celgene Customer Care Center at **1-888-423-5436**

   Male patients do not need to complete the initial survey.

   All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to REVLIMID REMS™ Program (formerly known as the RevAssist® program).
5. The prescriber completes mandatory confidential survey and receives authorization number by:
   - Visiting **www.CelgeneRiskManagement.com**, or
   - Calling Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes REVLIMID prescription and includes authorization number and patient risk category.
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the REVLIMID REMS™ procedures.

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.
Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((REVLIMID REMS™ logo)) ((REVLIMID logo))

((REVLIMID REMS logo))

Program for REVLIMID® (lenalidomide)
Education and Prescribing Safety

Dear Prescriber:

Enclosed are your REVLIMID REMS™ education materials.

Celgene Corporation is pleased to provide you with the enclosed materials for use in the REVLIMID REMS™ program (formerly known as the RevAssist® program).

Important Information about the REVLIMID REMS™ program

- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™"
- Lenalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with lenalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of lenalidomide in human semen. Male patients taking REVLIMID should not donate sperm. Males receiving REVLIMID must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with REVLIMID REMS™ can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMS™ program

As a prescriber certified with the REVLIMID REMS™ program, please review and familiarize yourself with the contents of the enclosed REVLIMID REMS™ Kit:

Prescriber Materials

- REVLIMID REMS™ software and Installation Guide
- Prescriber Guide to REVLIMID REMS™ Program
- REVLIMID Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to REVLIMID REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jerome B. Zeldis, MD, PhD
Chief Medical Officer

Enclosures

Risks of REVLIMID® (lenalidomide)

- REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or embryo-fetal death. REVLIMID must not be used by

pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

REVLIMID in combination with dexamethasone is indicated for the treatment of multiple myeloma (MM) patients who have received at least one prior therapy.

REVLIMID is indicated for patients with transfusion-dependent anemia due to Low- or Intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((REVLIMID REMS™ logo)) ((REVLIMID logo)

[Front Cover]

Pharmacy Guide to ((REVLIMID REMS™ logo)) Risk Evaluation and Mitigation Strategy (REMS)™ Program

Important information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ Program

- REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™" (formerly known as the RevAssist® program)
- Only prescribers and pharmacists certified with the REVLIMID REMS™ program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the REVLIMID REMS™ program
- Dispensing pharmacists must be educated on the REVLIMID REMS™ program and on dispensing procedures for REVLIMID
- Information about REVLIMID and the REVLIMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

((REVLIMID logo))

Table of contents

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide)

Dispensing pharmacies must be certified in the REVLIMID REMS™ program with Celgene and must be educated in the following dispensing procedures.

Step 1. Review incoming REVLIMID prescriptions

A. Only accept prescriptions with an authorization number and patient risk category written on them.
   - Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
   - Faxed prescriptions are permissible depending on state laws

B. Make sure the prescription is signed and dated.

C. Confirm the prescription is written for a 4-week (28-day) supply or less.

D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

Step 2. Counsel patient

A. Make sure a **certified REVLIMID REMS™** counselor counsels the patient.

B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.

C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID, make sure to document these experiences using acceptable documentation as noted on the checklist.

   - **Acceptable documentation examples:**

     1. Celgene ADE form and fax confirmation
     2. Pharmacy log

D. Report adverse drug experiences that are suspected to be associated with the use of REVLIMID to Celgene Drug Safety within 24 hours. See the "Adverse Drug Experience Reporting Procedure" on page 7 for more information.

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide) (continued)

Step 3. Obtain confirmation number from Celgene Customer Care

A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week.
- Enter the pharmacy NABP number or DEA number
- Enter the authorization number written on the prescription
- Enter the number of capsules and milligram strength being dispensed

B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.

C. If you do not obtain a confirmation number, do not dispense REVLIMID.

Step 4. Dispensing

A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**

B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.

C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.

- **Acceptable documentation examples:**
    1. Signed Education and Counseling checklist (if counseling pharmacist and dispensing pharmacist are the same)
    2. Pharmacy log

D. Document the dispense date and maintain a record on acceptable documentation.
- **Acceptable documentation examples:**
    1. Shipping receipt
    2. Pharmacy dispensing log

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide) (continued)

E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.
F. A signature is required for all shipping and dispense if picked up by patient.

Step 5. Perform drug accountability

A. Pharmacy shall keep an inventory log for REVLIMID, by strength, reflecting its on-hand inventory at all times.

B. Do not transfer REVLIMID to another pharmacy without prior authorization from Celgene.

C. Accept unused REVLIMID (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

REVLIMID Risk Evaluation Mitigation Strategy (REMS)™ education and counseling checklist for pharmacies

Ensure your patients know the risks

Before you are able to fill a prescription for REVLIMID ® (lenalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off ([✓]) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.

Be prepared to provide the following information for each checklist: ((IMAGE OF CHECKLIST))

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	Patient Identification Number

Rules for dispensing and shipping

Making sure before you release REVLIMID

DO NOT DISPENSE OR SHIP REVLIMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing REVLIMID prescription

For further information about REVLIMID, please refer to the full Prescribing Information, enclosed.

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of REVLIMID® (lenalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: **https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

[Back Cover]

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.
Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((REVLIMID REMS™ logo)) ((REVLIMID logo))

((REVLIMID REMS™ logo))

Education and counseling checklist for pharmacies

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program) education and prescribing safety

Authorization No.: Confirmation No.: Confirmation Date:
Pharmacy Name:
Pharmacy Address:
Counselor Name: Work Phone: Ext.:
Patient Name: Date of Birth: Patient I.D. No.:
Risk Category:

Checklist for female patients of reproductive potential

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

☐ Potential embryo-fetal toxicity

☐ Not taking REVLIMID® (lenalidomide) if pregnant or breastfeeding

☐ Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth controls pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male,** or abstaining from sex with a male

☐ Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking REVLIMID, while taking REVLIMID, during dose interruptions, and for at least 4 weeks after stopping REVLIMID **every time they have sex with a male**, or abstaining from sex with a male

☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks

☐ The need to stop taking REVLIMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately

☐ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism

☐ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID

☐ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant

☐ Not donating blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

☐ Not breaking, chewing, or opening REVLIMID capsules

☐ Instructions on REVLIMID dose and administration

Milligram (mg) Strength_____ Number of Capsules Dispensed_____

FEMALE CHILDREN (<18 YEARS OF AGE):

☐ Parent or legal guardian must have read the REVLIMID REMS™ education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

☐ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism

☐ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID

☐ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant

☐ Not donating blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

☐ Not breaking, chewing, or opening REVLIMID capsules

☐ Instructions on REVLIMID dose and administration

Milligram (mg) Strength_____ Number of Capsules Dispensed_____

FEMALE CHILDREN (<18 YEARS OF AGE):

☐ Parent or legal guardian must have read the REVLIMID REMS™ education material and agreed to ensure compliance

☐ Parent or legal guardian must inform the child's doctor when the child begins menses

Checklist for male patients

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

☐ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant)

☐ Female partners of males taking REVLIMID® (lenalidomide) must call their healthcare provider right away if they get pregnant

☐ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism

☐ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID

☐ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant

☐ Not donating blood or sperm while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

☐ Not breaking, chewing, or opening REVLIMID capsules

☐ Instructions on REVLIMID dose and administration

Milligram (mg) Strength_____ Numbers of Capsules Dispensed_____

MALE CHILDREN (<18 YEARS OF AGE):

☐ Parent or legal guardian must have read the REVLIMID REMS™ education material and agreed to ensure compliance

Rules for dispensing and shipping

DO NOT DISPENSE OR SHIP REVLIMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- ☐ Prescription has an authorization number and patient risk category written on it
- ☐ You have counseled the patient
- ☐ You have obtained a confirmation number and a confirmation date
- ☐ You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- ☐ The Medication Guide is included with the prescription
- ☐ You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing REVLIMID prescription

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: _____ Date: _____

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((REVLIMID REMS™ logo)) ((REVLIMID logo))

REVLIMID REMS™ Pharmacy Certification Quiz

1. Authorization numbers for females of reproductive potential are valid for up to _____ days: *(Mandatory Question)*
    a. **7 days**
    b. 10 days
    c. 14 days
    d. 28 days

2. It is not necessary to obtain a confirmation number to dispense. *(Mandatory Question)*
    a. True
    b. **False**

3. Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for each treatment. *(Mandatory Question)*
    a. **True**
    b. False

4. It is not required to retain the prescription with the authorization and confirmation numbers for each filled prescription. It is not necessary to complete the Education and Counseling Checklist.
    a. True
    b. **False**

5. According to the package insert's boxed warnings and warnings and precautions, neutropenia, thrombocytopenia, deep venous thrombosis, and pulmonary embolism have been reported in patients receiving REVLIMID. *(Mandatory Question)*
    a. **True**
    b. False

6. REVLIMID can cause serious birth defects. *(Mandatory Question)*
    a. **True**
    b. False

7. What pregnancy precautions are required for a female of reproductive potential with respect to heterosexual sexual contact?
    a. **Must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time she has sex with a male, beginning at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks after stopping therapy**
    b. Abstain from having any heterosexual sexual contact only while taking therapy
    c. After stopping therapy it is okay to get pregnant at any time
    d. Use 2 forms of birth control 2 weeks before taking therapy

8. What precautions are required for a male with respect to sexual contact with his female partner of reproductive potential?

a. **Use of a latex or synthetic condom every time he has sexual intercourse with a FRP during therapy (including dose interruptions) and for 4 weeks after stopping therapy, even if he has undergone a successful vasectomy**
b. Abstain from having any sexual contact with a female of reproductive potential only while taking therapy
c. Use latex or synthetic condoms while taking therapy. No precautions are necessary once treatment has stopped
d. Males taking therapy who have had a vasectomy do not need to use latex or synthetic condoms

9. For all Celgene REMS programs, female patients of reproductive potential must have a negative pregnancy test: *(Mandatory Question)*
    a. Prior to initial prescription
    b. Prior to subsequent prescription
    c. **Prior to initial prescription and prior to subsequent prescription**
    d. None of these

10. Adverse drug experiences that are suspected to be associated with the use of therapy, and any suspected pregnancy occurring during treatment, must be reported to Celgene. *(Mandatory Question)*
    a. **True**
    b. False

11. The Medication Guide must be provided every time REVLIMID is dispensed. *(Mandatory Question)*
    a. **True**
    b. False

12. A certified Celgene REMS pharmacy cannot dispense more than a _____supply of REVLIMID.
    a. **28 day**
    b. 3 month
    c. 2 week
    d. 1 year

13. Authorization numbers for patient risk categories other than females of reproductive potential are valid for up to _____ days. *(Mandatory Question)*
    a. **30 days**
    b. 10 days
    c. 7 days
    d. 28 days

14. A male patient can donate sperm at any time during therapy.
    a. True
    b. **False**

((REVLIMID REMS™ logo))

Patient Resource Pack

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program)

The Patient Resource Pack contains:

- Patient Guide to the REVLIMID REMS™ Program
- Emergency Contraception Brochure
- Medication Guide

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

((Celgene logo)) ((REVLIMID logo))

 1/13 REMS-REV12104

Patient Guide to
((REVLIMID REMS™ logo))
Risk Evaluation And Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of REVLIMID® (lenalidomide)
    - Birth defects (deformed babies) or death of an unborn baby
    - Low white blood cells (neutropenia) and low platelets (thrombocytopenia)
    - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
- The REVLIMID REMS™ Program
    - What females who can get pregnant need to know:
        - Birth control options
    - What females who can not get pregnant need to know
    - What males need to know

((REVLIMID logo))

Table of contents

Risks of REVLIMID® (lenalidomide)

REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or death to unborn babies. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

What is the REVLIMID REMS™ program?

To avoid serious risks to unborn babies, REVLIMID is only available under a restricted distribution program called the "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™" (formerly known as the RevAssist® program). Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID. In order to receive REVLIMID, patients must be enrolled in the REVLIMID REMS™ program and agree to follow the requirements.

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center toll-free at **1-888-423-5436.**

What do all patients need to know about the REVLIMID REMS™ program?

General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects
- REVLIMID® (lenalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle REVLIMID capsules
- Keep REVLIMID in a cool, dry place
- Do **not** donate blood while you are taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID
- Unused REVLIMID capsules should be returned for disposal to Celgene by calling **1-888-423-5436** or to your REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to you

What do females who can get pregnant need to know about the REVLIMID REMS™ program?

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says you understand that REVLIMID should not be used during pregnancy, and that you agree not to become pregnant while taking REVLIMID
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking REVLIMID
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for REVLIMID, and again within 24 hours before you receive your first prescription for REVLIMID. If you are pregnant, you cannot take REVLIMID
- You will have pregnancy tests before starting REVLIMID and while taking REVLIMID, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for REVLIMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing REVLIMID® (lenalidomide), your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options

1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control. Talk to your healthcare provider about the following acceptable birth control methods. See below.

Reliable Methods of Birth Control to Use Together

Highly effective birth control methods		Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	+	Male latex or synthetic condom Diaphragm Cervical cap

2. Use the 2 methods of birth control at the same time

- **Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

What do females who can get pregnant need to know about the REVLIMID REMS™ program? (continued)

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only birth control method that is 100% effective**

3. Unacceptable methods of birth control

- Progesterone-only "mini-pills"

IUD Progesterone T

- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for REVLIMID® (lenalidomide) and again within 24 hours before receiving your first prescription for REVLIMID. Both pregnancy tests must have a negative result

* A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

B. While taking REVLIMID® (lenalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- **Remember, not having sex is the only birth control method that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider:
  - Every week during the first 4 weeks of treatment, then
  - Every 4 weeks if your menstrual cycles are regular, or
  - Every 2 weeks if your cycles are irregular
  - If you miss your period or have unusual menstrual bleeding, or
  - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking REVLIMID immediately and call your healthcare provider right away

What do females who can get pregnant need to know about the REVLIMID REMS™ program? (continued)

- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking REVLIMID® (lenalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking REVLIMID
- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking REVLIMID® (lenalidomide)

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
  - For at least 4 weeks after stopping REVLIMID, or
  - Do not have any sex with a male for 4 weeks after stopping REVLIMID

See also “General guidelines” on page 5 for requirements for all patients.

What do females who can not get pregnant need to know about the REVLIMID REMS™ program?

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
  - You have been in natural menopause for at least 2 years, or
  - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting REVLIMID
- Before your healthcare provider can write your prescription for REVLIMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing REVLIMID® (lenalidomide), your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking REVLIMID

- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

See also "General guidelines" on page 5 for requirements for all patients.

What do males need to know about the REVLIMID REMS™ program?

- You must use a latex or synthetic condom, **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form. You must agree that while taking REVLIMID you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing REVLIMID, your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking REVLIMID

- You must use a latex or synthetic condom, **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only birth control method that is 100% effective**
- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must **not** donate sperm while taking REVLIMID® (lenalidomide) (including during breaks [dose interruptions])
- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking REVLIMID

- For 4 weeks after receiving your last dose of REVLIMID, you must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping REVLIMID

See also "General guidelines" on page 5 for requirements for all patients.

Mandatory confidential patient surveys

As a patient who is enrolled in the REVLIMID REMS™ program for REVLIMID® (lenalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

Female children

- Initial survey before first prescription
- Monthly

Males

- No initial survey
- Monthly

Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a REVLIMID REMS™ certified pharmacy. The REVLIMID REMS™ certified pharmacy will contact you to discuss your REVLIMID® (lenalidomide) therapy. You will not receive your medication until you speak with the REVLIMID REMS™ certified pharmacy
- For more information, contact the Celgene Customer Care Center at **1-888-423-5436**

Warning to patients taking REVLIMID® (lenalidomide)

Attention females:

Do **not** take REVLIMID if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID.

Attention all patients:

You must **not** donate blood while taking REVLIMID® (lenalidomide), during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects.

REVLIMID must be kept out of the reach of children. Return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**, or to your REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to you.

You may require regular blood tests during REVLIMID treatment. Consult with your healthcare provider.

[Back Cover]

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

((Celgene logo)) ((REVLIMID REMS™ logo)) ((REVLIMID logo))

Patient Survey Reminder Card

Celgene logo **REMS Patient Survey Reminder**

Patient Name_____ **Date Survey Available**_____

_____

Doctor Office Contact and Phone #_____

Product_____ **Pharmacy Name**_____

_____ **Telephone Survey** **OR** **Website Survey**

From a touchtone phone dial
1-888-423-5436

Para español, oprime el numero dos

Press 2

to identify that you are a patient

Press 1

to take a survey

Press 1

Enter your 9-digit patient identification number (the number you provided during the enrollment process – for example your Social Security Number).

From the menu provided, select the drug that you have been prescribed.

Press 1 OR Press 2 OR Press 3

Your survey will then begin. Please answer all of the questions. Confirmation that the survey has been completed will be provided at the end of your survey.

Access the internet and type in the website address

www.CelgeneRiskManagement.com

You are not required to have a User Name or Password to complete a survey. To take your survey, left click your mouse on the button

You will be asked for the following information. Please enter the information exactly as it was provided during your enrollment process

After entering the information above, click

Survey questions will be displayed 1 per page. Please be sure to complete the survey in its entirety. A summary page displaying your survey answers will be displayed at the end of your survey. Upon completion, send the survey to Celgene by clicking

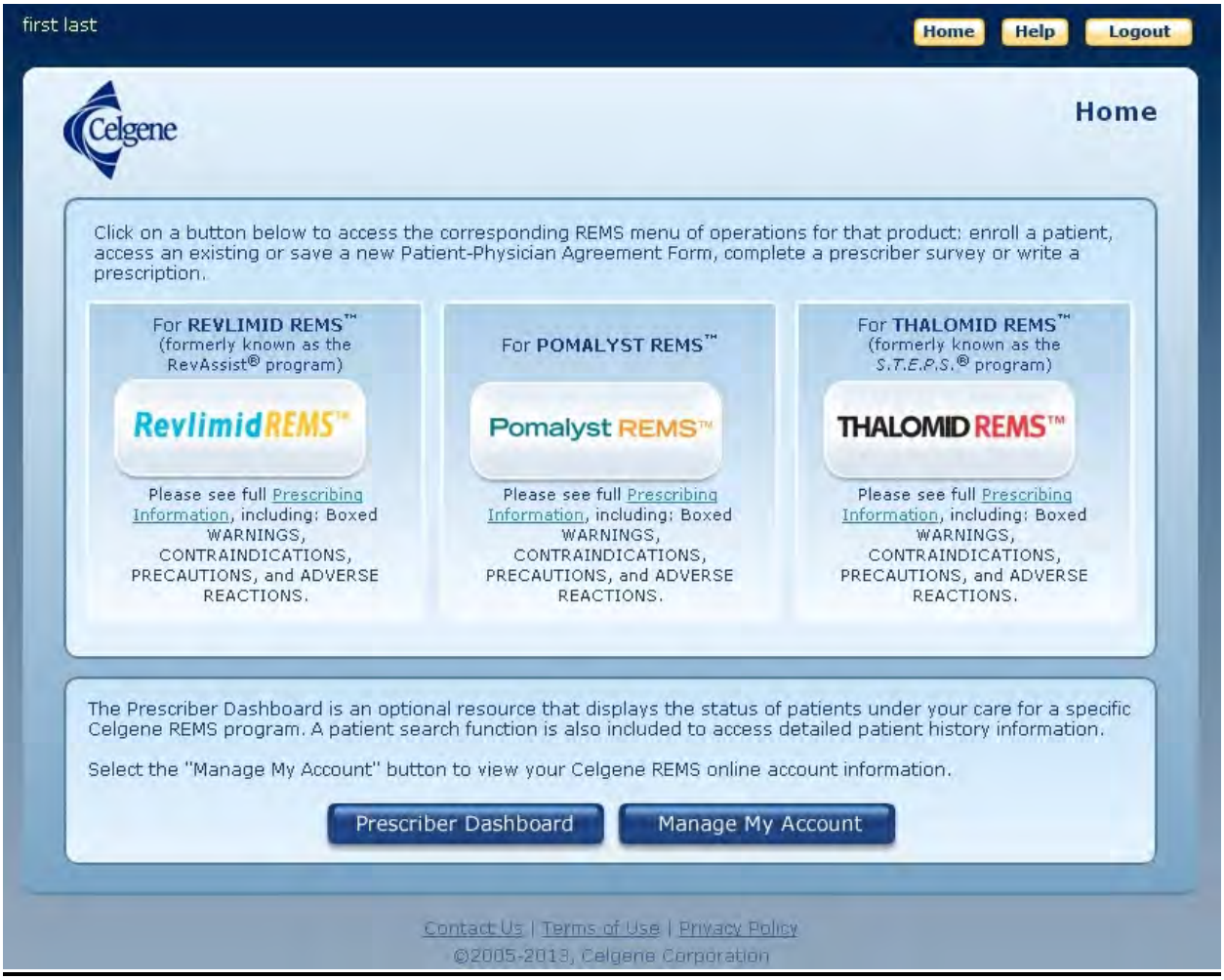
1/13

REMS-GEN12169

CelgeneRiskManagement.com

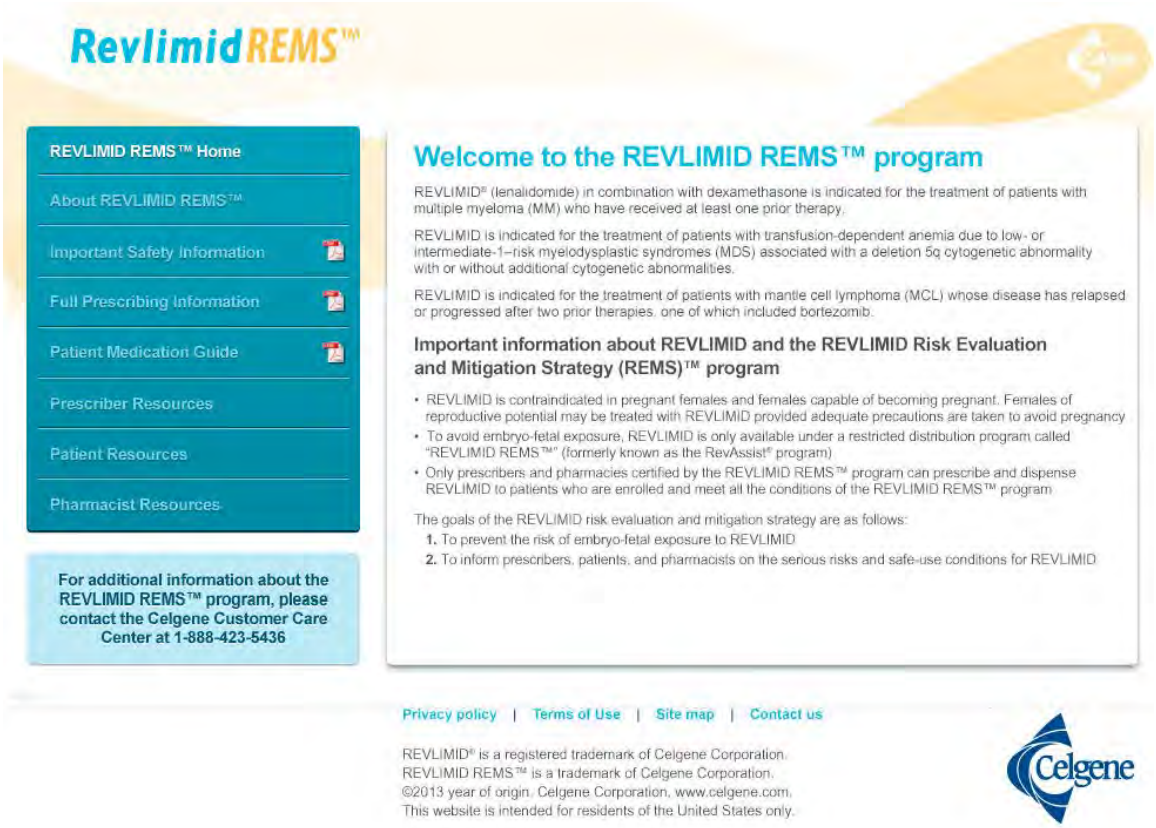
Login Page

Home Page (after prescriber logon)



REVLIMID REMS module

www. REVLIMIDREMS.com Web site




RevlimidREMS™
REVLIMID REMS™ Home
About REVLIMID REMS™
Important Safety Information
Full Prescribing Information
Patient Medication Guide
Prescriber Resources
Patient Resources
Pharmacist Resources
For additional information about the REVLIMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436
About the REVLIMID REMS™ program
REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.
REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.
To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™" (formerly known as the RevAssist® program). Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID in the REVLIMID REMS™ program.
In order to receive REVLIMID, all patients must be enrolled in the REVLIMID REMS™ program and agree to comply with the requirements of the REVLIMID REMS™ program.
Key points of the REVLIMID REMS™ program
Prescriber
• The prescriber enrolls and becomes certified with Celgene for the REVLIMID REMS™ program
• The prescriber counsels patient on benefits and risks of REVLIMID
• The prescriber provides contraception and emergency contraception counseling
• The prescriber verifies negative pregnancy test for all female patients of reproductive potential
• The prescriber completes a REVLIMID® (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
• The prescriber/patient completes applicable mandatory confidential survey
• The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
• The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
• The prescriber sends REVLIMID prescription to certified pharmacy
Pharmacy
• The pharmacy certifies with Celgene for the REVLIMID REMS™ program
• The certified pharmacy must obtain a confirmation number from Celgene before dispensing
• The certified pharmacy counsels the patient, and completes an Education and Counseling Checklist
• The certified pharmacy dispenses REVLIMID to patient along with a Medication Guide
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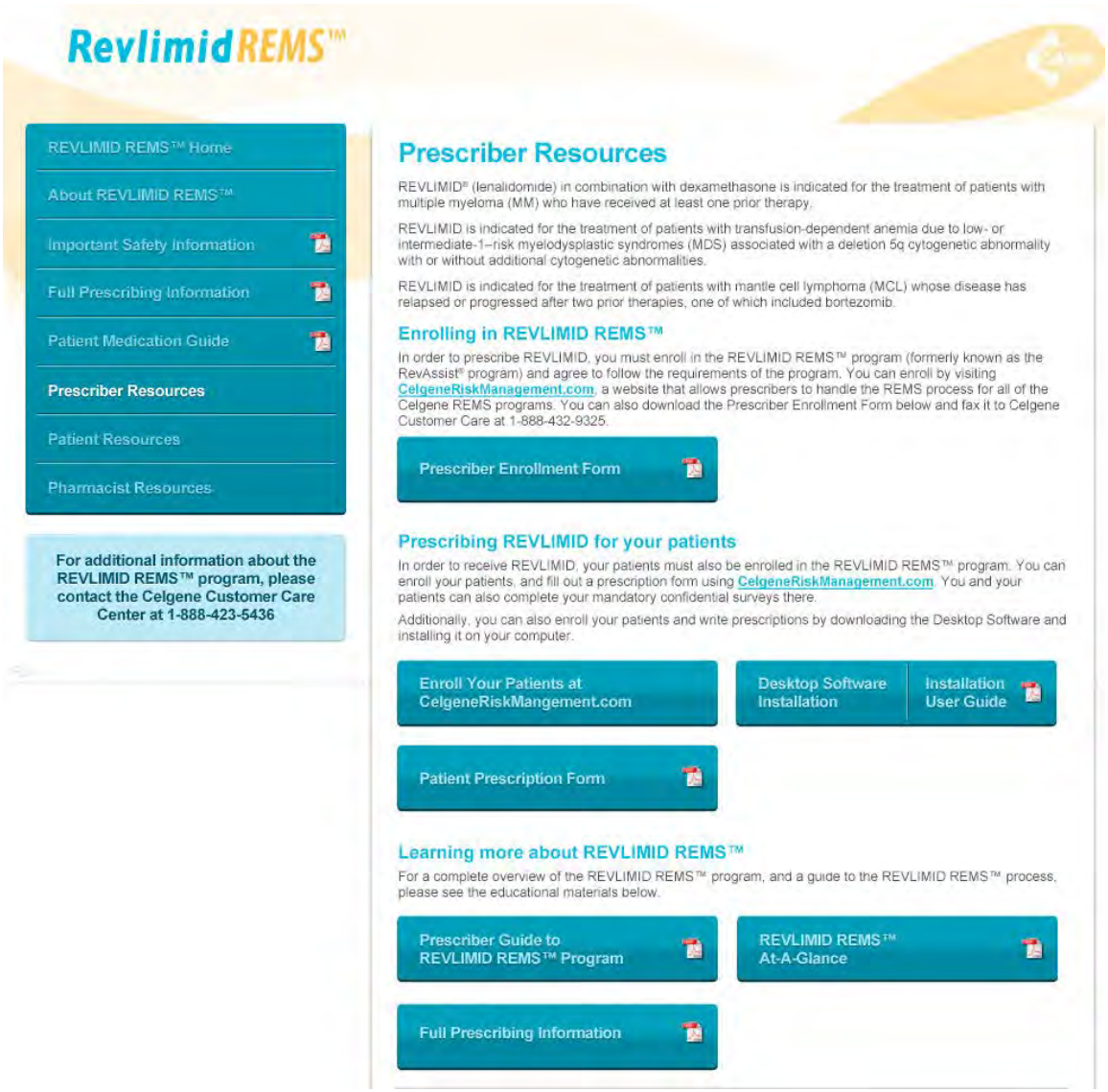
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Patient Resources
Pharmacist Resources
For additional information about the REVLIMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436
Prescriber Resources
REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.
REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.
Enrolling in REVLIMID REMS™
In order to prescribe REVLIMID, you must enroll in the REVLIMID REMS™ program (formerly known as the RevAssist® program) and agree to follow the requirements of the program. You can enroll by visiting CelgeneRiskManagement.com, a website that allows prescribers to handle the REMS process for all of the Celgene REMS programs. You can also download the Prescriber Enrollment Form below and fax it to Celgene Customer Care at 1-888-432-9325.
Prescriber Enrollment Form
Prescribing REVLIMID for your patients
In order to receive REVLIMID, your patients must also be enrolled in the REVLIMID REMS™ program. You can enroll your patients, and fill out a prescription form using CelgeneRiskManagement.com. You and your patients can also complete your mandatory confidential surveys there.
Additionally, you can also enroll your patients and write prescriptions by downloading the Desktop Software and installing it on your computer.
Enroll Your Patients at CelgeneRiskMangement.com
Desktop Software Installation
Installation User Guide
Patient Prescription Form
Learning more about REVLIMID REMS™
For a complete overview of the REVLIMID REMS™ program, and a guide to the REVLIMID REMS™ process, please see the educational materials below.
Prescriber Guide to REVLIMID REMS™ Program
REVLIMID REMS™ At-A-Glance
Full Prescribing Information

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods:

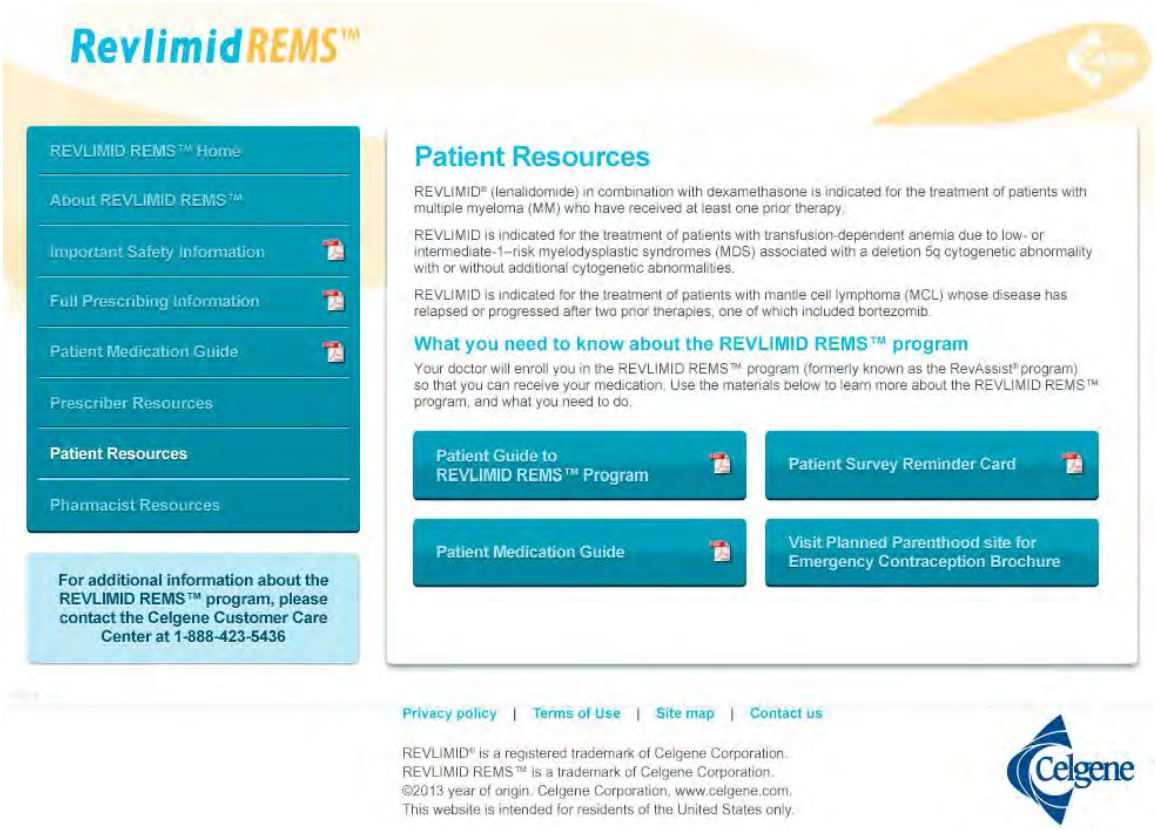
REPORTING TO CELGENE

Email:	drugsafety@celgene.com
Telephone:	1-908-673-9667
Toll-free:	1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
Fax:	1-908-673-9115
Mail to:	Global Drug Safety & Risk Management Celgene Corporation 300 Connell Dr. Suite 6000 Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

Online:	https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
Telephone:	1-800-332-1088
Fax:	1-800-332-0178
Mail to:	MedWatch 5600 Fishers Lane Rockville, MD 20852-9787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Prescriber Resources
Patient Resources
Pharmacist Resources
For additional information about the REVLIMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436
Patient Resources
REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.
REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.
What you need to know about the REVLIMID REMS™ program
Your doctor will enroll you in the REVLIMID REMS™ program (formerly known as the RevAssist® program) so that you can receive your medication. Use the materials below to learn more about the REVLIMID REMS™ program, and what you need to do.
Patient Guide to REVLIMID REMS™ Program
Patient Survey Reminder Card
Patient Medication Guide
Visit Planned Parenthood site for Emergency Contraception Brochure
Privacy policy | Terms of Use | Site map | Contact us
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RevlimidREMS™

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- Patient Medication Guide
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- **Pharmacist Resources**

For additional information about the REVLIMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

Pharmacist Resources

REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

REVLIMID REMS™ information for certified pharmacies

REVLIMID is only dispensed from REVLIMID REMS™ program (formerly known as the RevAssist® program) certified pharmacies. To learn more about how to become a certified pharmacy please contact the Celgene Customer Care at 1-888-423-5436.

As a REVLIMID REMS™ certified pharmacy, you must follow the requirements of the REVLIMID REMS™ program. You may download a guide to the program, a checklist for counseling patients, and the full prescribing information below.

Pharmacy Guide to REVLIMID REMS™ Program

Education and Counseling Checklist for Pharmacies

Full Prescribing Information

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods:

REPORTING TO CELGENE	
Email:	drugsafety@celgene.com
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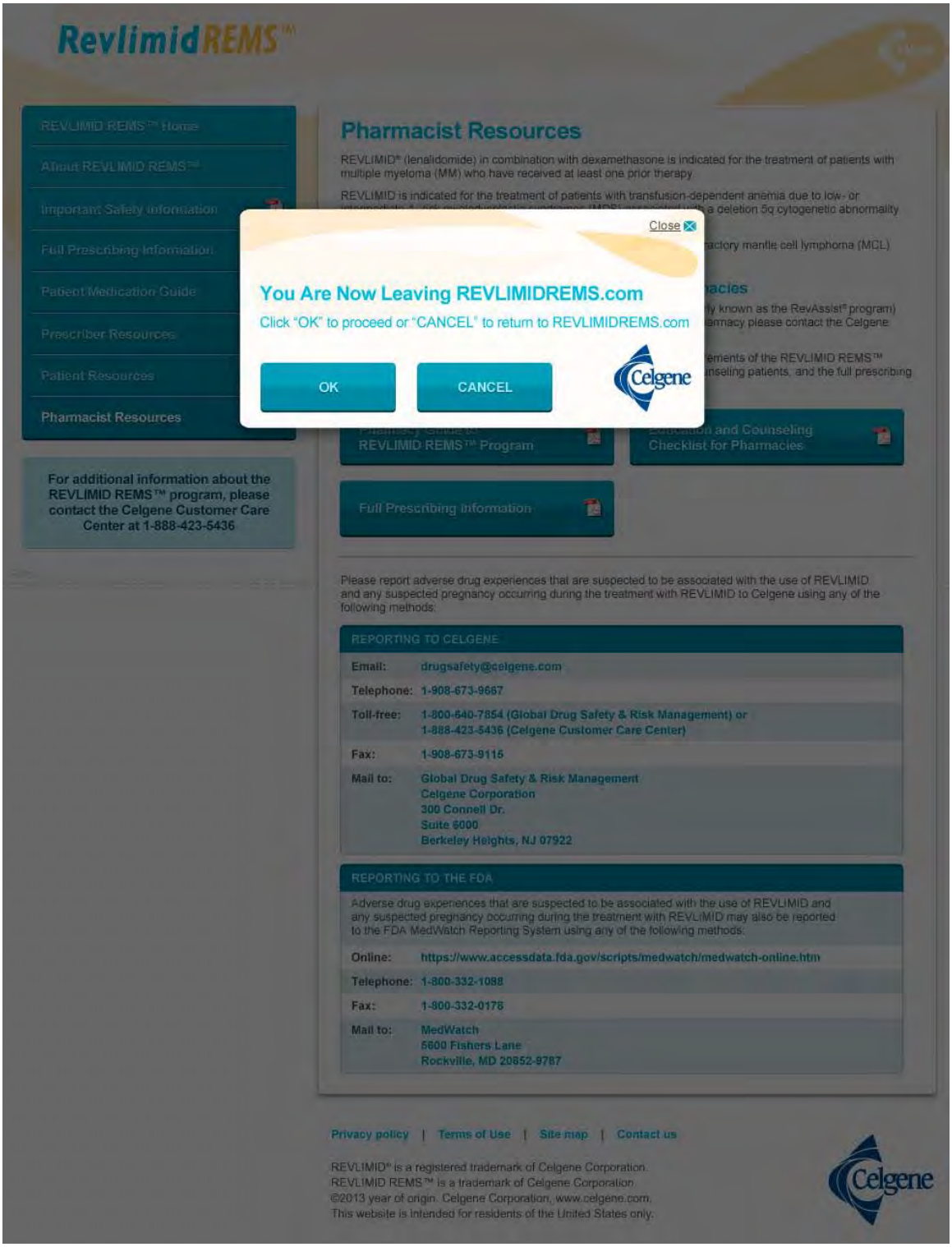
Fax:	1-908-673-9115
Mail to:	Global Drug Safety & Risk Management Celgene Corporation 300 Connell Dr. Suite 6000 Berkeley Heights, NJ 07922

REPORTING TO THE FDA	
Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:	
Online:	https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
Telephone:	1-800-332-1088
Fax:	1-800-332-0178
Mail to:	MedWatch 5600 Fishers Lane Rockville, MD 20852-9787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Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
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Mail to: Global Drug Safety & Risk Management
Celgene Corporation
300 Connell Dr.
Suite 6000
Berkeley Heights, NJ 07922
REPORTING TO THE FDA
Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:
Online: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
Telephone: 1-800-332-1088
Fax: 1-800-332-0178
Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787
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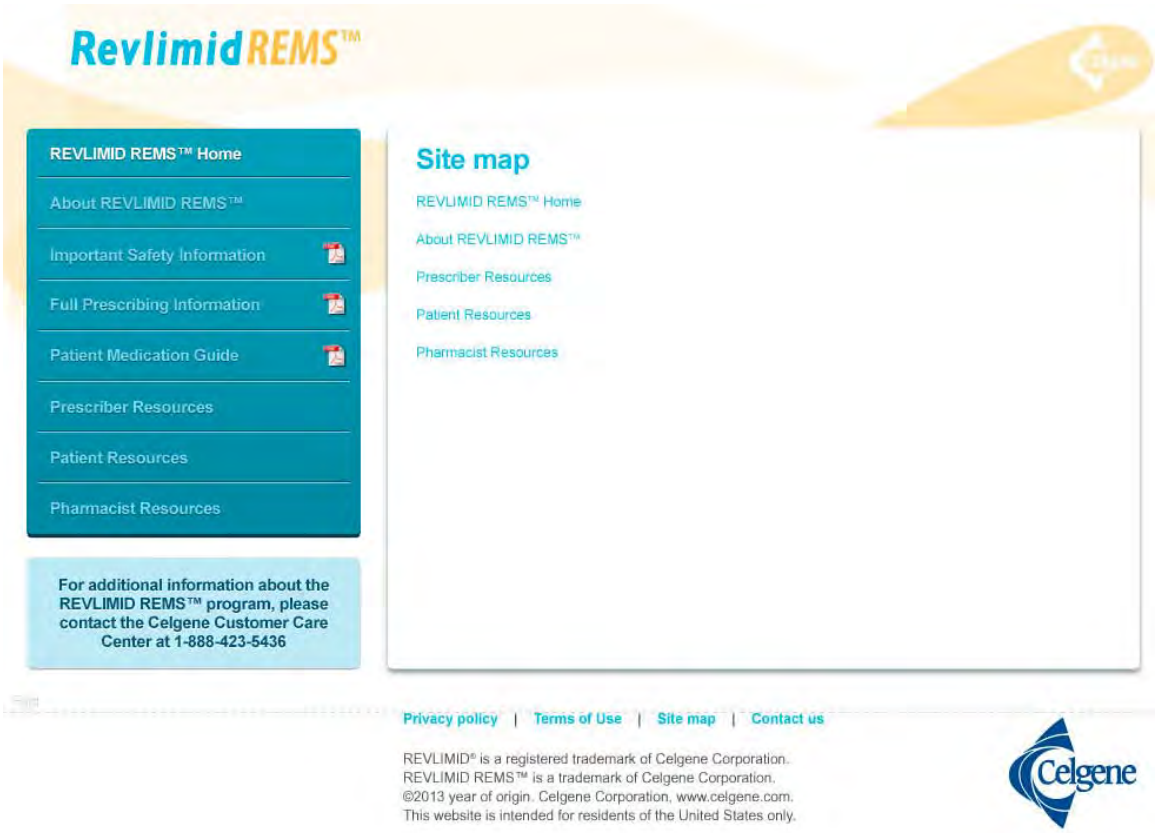
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REVLIMID® (lenalidomide) Pregnancy Exposure Registry

Version 2

Celgene Corporation
86 Morris Ave.
Summit, NJ 07901

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1. INTRODUCTION

The goal of the program is to minimize the risk of embryo-fetal exposure to REVLIMID® (lenalidomide) due to the potential of embryo-fetal toxicity. The drug is contraindicated in female patients who are or may become pregnant.

Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen with an active pharmaceutical ingredient that causes severe life-threatening birth defects. An embryo-fetal development study in non-human primates indicates that lenalidomide produces malformations in the offspring of female monkeys who received the drug during pregnancy, similar to birth defects observed in humans following exposure to thalidomide during pregnancy. The teratogenic effect of lenalidomide in humans cannot be ruled out.

1.1. REVLIMID Pregnancy Prevention REMS Program

Because of the potential teratogenic effects of REVLIMID and to avoid embryo-fetal exposure, REVLIMID is available only under the REVLIMID REMS™ program (formerly known as the RevAssist® program).Under this program, only prescribers and pharmacies certified with the program REVLIMID are able to prescribe and dispense the product.

In addition, REVLIMID must be dispensed only to patients who are enrolled and meet all the conditions of the REVLIMID REMS™ program. Certified pharmacies and/or pharmacists are the only authorized healthcare providers allowed to dispense prescriptions of REVLIMID to patients and are required to educate and direct the patient to REVLIMID educational materials and the Medication Guide.

Prescribers must complete a mandatory survey through Celgene to obtain an authorization number for each prescription written. Patients must periodically take part in a mandatory, confidential survey to help ensure that they receive, understand and can follow information on preventing embryo-fetal exposure. In the REVLIMID REMS™ program, a female of reproductive potential (FRP) is defined as a sexually mature female who has not undergone a hysterectomy, bilateral oophorectomy, or who has not been postmenopausal naturally for at least 24 consecutive months (i.e., who has had menses at some time in the preceding 24 consecutive months). Enrolled FRP need to complete a brief, confidential survey monthly before a prescription can be written for the medication. A REVLIMID REMS™ certified pharmacy will contact the patient by phone to discuss REVLIMID therapy. The patient will not receive the medication unless she speaks with the REVLIMID REMS™ certified pharmacy. The FRP must have a thorough understanding of the need for 2 of the recommended forms of birth control beginning at least 4 weeks before therapy, and continuing during therapy (including any necessary dose interruptions) and for at least 4 weeks following discontinuation of therapy with REVLIMID. The FRP must have negative pregnancy tests (1) within 10 to 14 days and (2) within 24 hours prior to receiving an initial prescription for REVLIMID. Pregnancy tests must be sensitive to 50 mIU/mL. A pregnancy test is to be performed weekly during the first 4 weeks, and then repeated every 4 weeks among FRP with regular menstrual cycles. If menstrual cycles are irregular, testing should occur every 2 weeks. In the event of pregnancy, the FRP should discontinue REVLIMID®. Pregnancy testing and counseling should be performed if a patient misses her period or if there is any abnormality in her pregnancy test or in her menstrual

bleeding. All cases of pregnancy should be reported to FDA MedWatch at 1-800-FDA-1088 and to Celgene at 1-888-423-5436.

1.2. Full Prescribing Information

The full prescribing information states that pregnancy test results should be verified by the prescriber and the pharmacist prior to dispensing any prescription. If a pregnancy does occur during REVLIMID treatment, REVLIMID must be discontinued immediately. Any suspected embryo-fetal exposure to REVLIMID should be reported to the FDA via the MedWatch number at 1-800-FDA-1088 and also to Celgene Corporation at 1-888-423-5436.

The Medication Guide (Information for Patients and Caregivers), which is a part of the prescribing information, noted that female partners of males taking REVLIMID should call their health care provider right away if they get pregnant and patients who get pregnant should stop taking REVLIMID right away and call their health care provider. Health care providers and patients should report all cases of pregnancy to FDA MedWatch at 1-800-FDA-1088 and to Celgene Corporation at 1-888-423-5436.

2. OBJECTIVE

Celgene is committed to investigating any reports of possible embryo-fetal exposure to REVLIMID® (lenalidomide) whether it is the patient or the patient's partner.

The objectives of the REVLIMID Pregnancy Exposure Registry are:

- to monitor pregnancy outcomes (should one occur) in female patients of reproductive potential and female partners of patients who are exposed to REVLIMID and
- to understand the root cause for the pregnancy.

3. METHODS

Pregnancy is identified as any of the following:

- Pregnancy of a patient
- Pregnancy of a female partner of a patient taking REVLIMID®

Reports of pregnancy may be received from the REVLIMID REMS™ program in the United States, Celgene Pregnancy Prevention Plan programs in the rest of the world (ROW), company representatives, clinical trials (US and ROW), or directly from consumer and health care professionals. Specifications for handling pregnancy reports are included in every Celgene study protocol. All reports of pregnancy in a female patient or partner of patient will be actively monitored. Contact information of health care providers and patients will be retrieved from Celgene Order Management System (COMS) database for reports from the commercial environment and from Celtrak (repository of study information) for reports from clinical trials. Health care providers (HCP, clinical trial investigator, prescriber, obstetrician, neonatologist, pediatrician) will be contacted to obtain pregnancy background, pregnancy outcome, pregnancy follow-up and infant outcome information; patients and male patients of pregnant partners will be contacted (when appropriate) to obtain pregnancy information to the extent permitted by local regulations/laws will permit. A letter with the Pregnancy Background Form will be sent initially to the health care provider (prescriber, clinical trial investigator, and obstetrician) and a letter with the Pregnancy Follow-up Form will be sent every trimester or until the outcome is known. A letter with the Pregnancy Form for patient or male patient of pregnant partner will be sent (when appropriate) within 30 days after a report of a confirmed pregnancy. A letter with the Pregnancy Outcome Form for HCP (prescriber, clinical trial investigator, obstetrician, neonatologist, and pediatrician) will be sent within 30 days after expected delivery. A letter with the Pregnancy Outcome Form for patient/male patient of partner will be sent (when appropriate) within 30 days after expected delivery. A letter with the Infant Follow-up Form will be sent to the pediatrician or primary care physician every quarter until the infant is a year old.

All pregnancy cases are entered in the Global Drug Safety database. The Drug Safety Specialist (DSS) or designee will process the completed forms and follow-up with the HCP and patient or male patient of pregnant partner.

The following forms will be used to monitor the pregnancy and pregnancy outcome:

- Pregnancy Background Form for HCP,
- Pregnancy Follow-up Form for HCP,
- Pregnancy Outcome Form for HCP,
- Pregnancy Background Form for Patient or Male Patient of Pregnant Partner
- Pregnancy Outcome Form for Patient or Male Patient of Pregnant Partner, and
- Infant Follow-up Form for Primary Care Physician or Pediatrician.

The Pregnancy Background Form for Patient or Male Patient of Pregnant Partner will be utilized for the root cause analysis of pregnancy. The letters and the forms are found in Appendix 1 and the definition of terms is found in Appendix 2.

The processes are presented in Figure 1, Figure 2 and Figure 3.

3.1. Pregnancy/Pregnancy Background

3.1.1. Health Care Providers

- When a pregnancy is reported, the Drug Safety Specialist (DSS) or designee will make an outbound call to the reporter to verify the pregnancy. If there is no response, the DSS or designee will make another outbound call to the reporter to verify the pregnancy.
- If the pregnancy is verified, the DSS will generate a letter and a Pregnancy Background Form that will be sent to the health care provider (HCP; prescriber, clinical investigator, obstetrician, primary care physician).
- If no response is received within 30 days, the letter and Pregnancy Background Form will be resent.
- If there is no response to the second letter within 30 days, an outbound call will be made to the HCP (prescriber, clinical investigator, obstetrician, primary care physician) requesting that the Pregnancy Background Form be completed.
- If there is no response to the outbound call from the obstetrician/primary care physician within 30 days, all contacts and attempts will be documented in the case.
- If there is no response to the outbound call from the clinical investigator, the clinical study manager will be contacted to assist in obtaining the response from the clinical investigator.
- If there is no response to the outbound call from the prescriber within 30 days, he or she will be flagged. When the flagged prescriber request for a prescription authorization, the call will be directed to the DSS or designee who will remind the prescriber to complete the Pregnancy Background Form.
- If there is no response within 30 days, the DSS or designee will document all contacts and attempts. If the completed Pregnancy Background Form is received, the DSS or designee will unflag the Prescriber.
- The DSS or designee will process the completed Pregnancy Background Form.

3.1.2. Patient and Male Patient of Pregnant Partner

- A letter and a Pregnancy Background Form for patient and male patient of pregnant partner will be sent (when appropriate) within 30 days after a report of confirmed pregnancy to patients enrolled in the REVLIMID REMS™ program. The letter and the form for patient and male patient of pregnant partner will be sent to the clinical investigator for completion of the study subject at the next study visit. The Pregnancy Background Form will collect information for the root cause analysis of pregnancy.
- If no response is received within 30 days, the letter and Pregnancy Background Form will be resent.

- If there is no response to the second letter within 30 days, an outbound call will be made to the patient/male patient of pregnant partner for patients enrolled in the REVLIMID REMS™ program requesting that the Pregnancy Background Form be completed and to the clinical investigator to remind the study subject to complete the form at the next study visit.
- If there is no response to the outbound call from the patient/male patient of pregnant partner within 30 days, the study manager will be contacted to assist in obtaining the response.
- If there is no response to the outbound call from the patient/male patient of pregnant partner within 30 days, all contacts and attempts will be documented in the case.
- The DSS or designee will process the completed Pregnancy Background Form.

3.2. Pregnancy Follow-up

- A Pregnancy Follow-up Form will be sent to the obstetrician/primary care physician every trimester or until the outcome is known.
- If the obstetrician/primary care physician does not respond within 30 days, the letter and Pregnancy Follow-up Form will be resent.
- If there is no response to the second letter, an outbound call will be made to the obstetrician/primary care physician requesting the completion of the Pregnancy Follow-up Form.
- If no response is received within 30 days, all contacts and attempts will be documented in the case.
- The DSS or designee will process the completed Pregnancy Follow-up Form.

3.3. Pregnancy Outcome

3.3.1. Health Care Providers

- For confirmed pregnancies, Pregnancy Outcome Form for HCP (prescriber, clinical investigator, obstetrician, neonatologist, pediatrician, primary care physician) will be sent within 30 days after the expected date of delivery.
- If the HCP (prescriber, clinical investigator, obstetrician, neonatologist, pediatrician, primary care physician) does not respond within 30 days, the letter and Pregnancy Outcome Form will be resent.
- If there is no response to the second letter, an outbound call will be made to the HCP (prescriber, clinical investigator, obstetrician, neonatologist, pediatrician, primary care physician) requesting the completion of the Pregnancy Outcome Form.
- If there is no response from the clinical investigator, the study manager will be contacted to assist in obtaining the response.

- If there is no response from the obstetrician/neonatologist/pediatrician/primary care physician/clinical investigator within 30 days, all contacts and attempts will be documented in the case.
- If there is no response from the Prescriber within 30 days, the prescriber will be flagged. When the flagged prescriber request for a prescription authorization, the call will be directed to the DSS or designee who will remind the prescriber to complete the Pregnancy Outcome Form.
- If there is no response within 30 days, the DSS or designee will document all contacts and attempts. If the completed Pregnancy Outcome Form is received, the DSS or designee will unflag the Prescriber.
- The DSS or designee will process the completed Pregnancy Outcome Form.

3.3.2. Patient and Male Patient of Pregnant Partner

- A Pregnancy Outcome Form for patient and male patient of pregnant partner will be sent (when appropriate) within 30 days after the expected date of delivery.
- If the patient and male patient of pregnant partner do not respond within 30 days, the letter and Pregnancy Outcome Form will be resent.
- If there is no response to the second letter, an outbound call will be made to the patient and male patient of pregnant partner requesting the completion of the Pregnancy Outcome Form.
- If no response is received within 30 days, all contacts and attempts will be documented in the case.
- The DSS or designee will process the completed Pregnancy Outcome Form.

3.4. Infant Follow-up

- The DSS or designee will send a letter and an Infant Follow-up Form to the primary care physician or pediatrician quarterly until the infant is a year old. The first letter will be sent 3 months after birth.
- If there is no response within 30 days, the DSS or designee will re-send the letter and the Infant Follow-up Form.
- If there is no response to the second letter, an outbound call will be made to the primary care physician or pediatrician requesting the completion of the Infant Follow-up Form.
- If no response is received within 30 days, all contacts and attempts will be documented in the case.
- The DSS or designee will process the completed Infant Follow-up Form.

4. DATA ANALYSIS

Descriptive statistics will be the primary approach for summarizing data from the pregnancy exposure registry.

Subjects' age, duration of lenalidomide treatment, and weeks of gestational age at exposure will be summarised using descriptive statistics for continuous variables, while gender, indication for lenalidomide use, concomitant medications, type of delivery, pregnancy outcome, obstetrical history, adverse events during pregnancy, embryo-fetal outcome, infant status, and cytogenetic abnormalities will be summarised with descriptive statistics appropriate for categorical data. The information will be separately provided for female patients and for male patients and their pregnant partners as appropriate for the variable of interest.

The pregnancy proportion for female of reproductive potential (FRP) will be determined by dividing the total number of FRP experiencing at least one pregnancy over the total FRP population. The pregnancy proportion will be stratified by prescribing environment (e.g., patients exposed to commercially marketed lenalidomide, patients exposed to lenalidomide in clinical trials under IND applications]. Because of the unique denominator data available in the United States, these analyses will be conducted separately for patients in the REVLIMID REMS™ program. Patients with more than one exposed pregnancy will be tabulated.

The Pregnancy Background Form completed by the patient or male patient of pregnant partner will be utilized to analyze root cause for the pregnancy. The forms of birth control; unprotected sex; reasons for unprotected sex; receipt, reading, and understanding of the medication guide, source of knowledge about contraception, and understanding of the risk of pregnancy during lenalidomide use will be summarized with descriptive statistics.

The CDC birth defects code list will be used for classifying any reported congenital anomalies.

5. INDIVIDUAL CASE REPORTS

Initial pregnancy cases must be reported (notification) to the FDA within 24 hours of receipt followed by a 15-day alert report. Any follow-up information received must be submitted as a follow-up 15-day alert report.

For all Celgene products where there is a regulatory commitment for 24-hour notification (i.e., lenalidomide, thalidomide) or a requirement in the clinical study protocol for immediate notification, all Celgene personnel, including affiliates and licensed partners, shall inform Global Drug Safety or the appropriate Celgene Drug Safety department worldwide **IMMEDIATELY** by a telephone call followed by electronic transmission (email or facsimile) of a serious adverse event report of any possible exposure of a pregnant woman to the Celgene product.

6. STATUS REPORTS

The status report will be included in the REVLIMID® periodic safety report. The status report will include the following:

- Number of pregnancies in patients and partners of patients with outcome known (stratified by live birth, spontaneous abortions, elective terminations, fetal deaths/stillbirths)
- Number of pregnancies with outcome pending
- Number of pregnancies lost to follow-up
- Pregnancy proportions for FRP patients and for male patients, stratified by prescribing environment
- Number of females of reproductive potential exposed for postmarketing and clinical trials (US and ROW*) during the time period
- Number of males exposed for postmarketing and clinical trials (US and ROW*) during the time period

*Note: REVLIMID REMS™ is unique to the United States. In other countries where REVLIMID is marketed, such controlled distribution may not be possible because of legal restraints. Hence, accurate data on patient demographics will not be available.

For pregnancies with known outcome, the status report will include line listings and summaries of:

- Demographics, obstetrical and medical history of mothers
- Weeks of gestational age at exposure
- Type, dose and duration of exposure
- Weeks of gestational age at completion or termination of pregnancy
- For live births and deaths/stillbirths, whether multiple birth, small for gestational age, pre-term delivery and congenital anomalies or other fetal abnormalities
- For spontaneous abortions and elective terminations, abnormalities in products of conception

7. REGISTRY DISCONTINUATION

The pregnancy registry will be evaluated annually to determine if the feasibility of collecting information has diminished to unacceptable levels because of low exposure rates or loss to follow-up

8. REFERENCES

CDC. Metropolitan Atlanta Congenital Defects Program Procedure Manual. 1993;A32-A100(77):488-7160.

EMEA Committee for Medicinal Products for Human Use: *Guideline on the Exposure to Medicinal Products During Pregnancy: Need for Post-Authorization Data.* London, UK. 14Nov2005.

Food and Drug Administration. *Guidance for Industry Establishing Pregnancy Exposure Registries*. Rockville, MD. August 2002.

Investigator's Brochure for Lenalidomide ver 9. Summit, NJ: Celgene Corporation, 8Mar2006.

REVLIMID® [Full Prescribing Information and the Medication Guide]. Summit, NJ: Celgene Corporation; 2005.

REVLIMID REMS™ Program for REVLIMID® education and prescribing safety.

Figure 1: Pregnancy Background and Follow -Up Process Flow - HCP

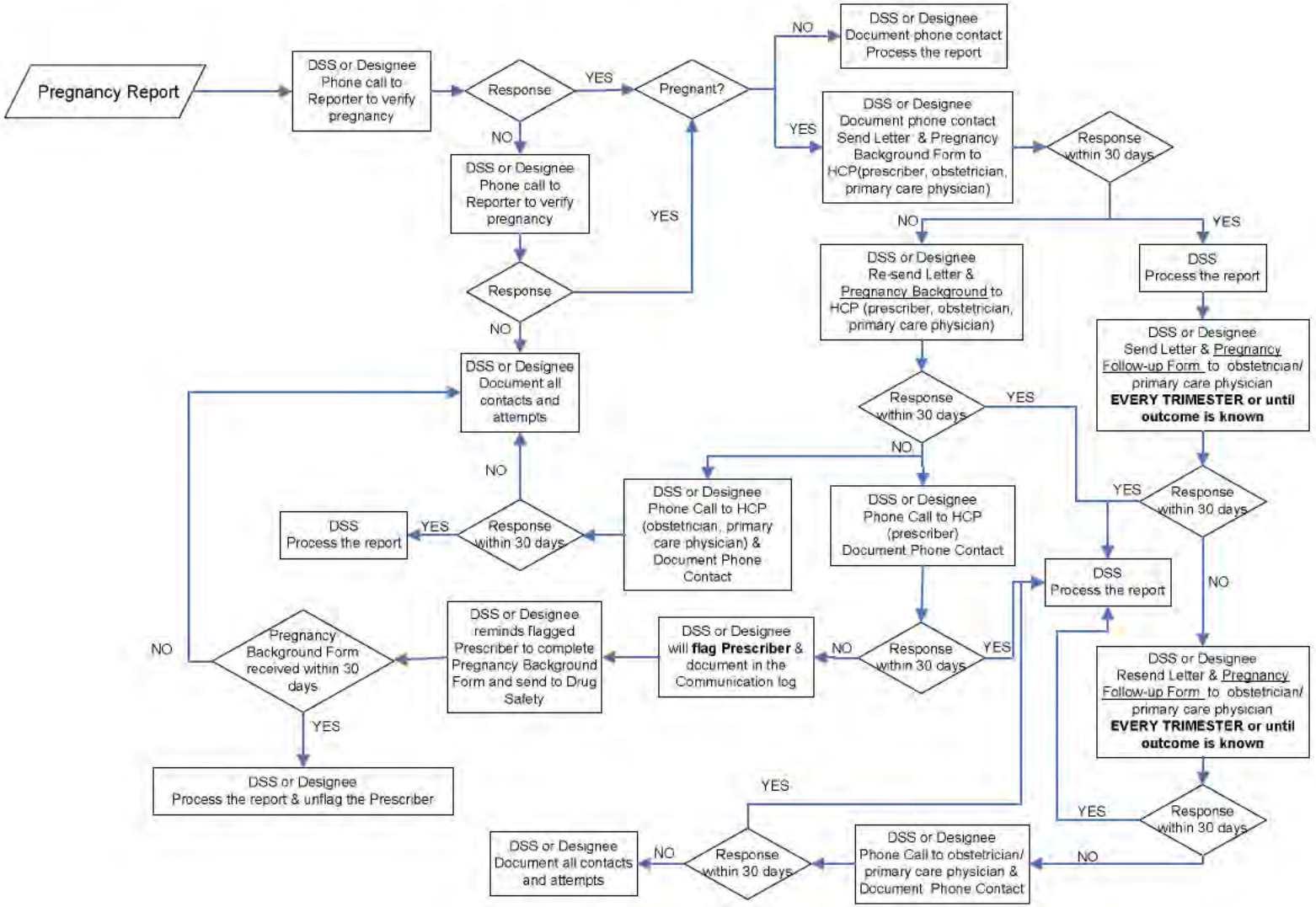


Figure 2: Pregnancy Outcome and Infant Follow -Up Process Flow - HCP

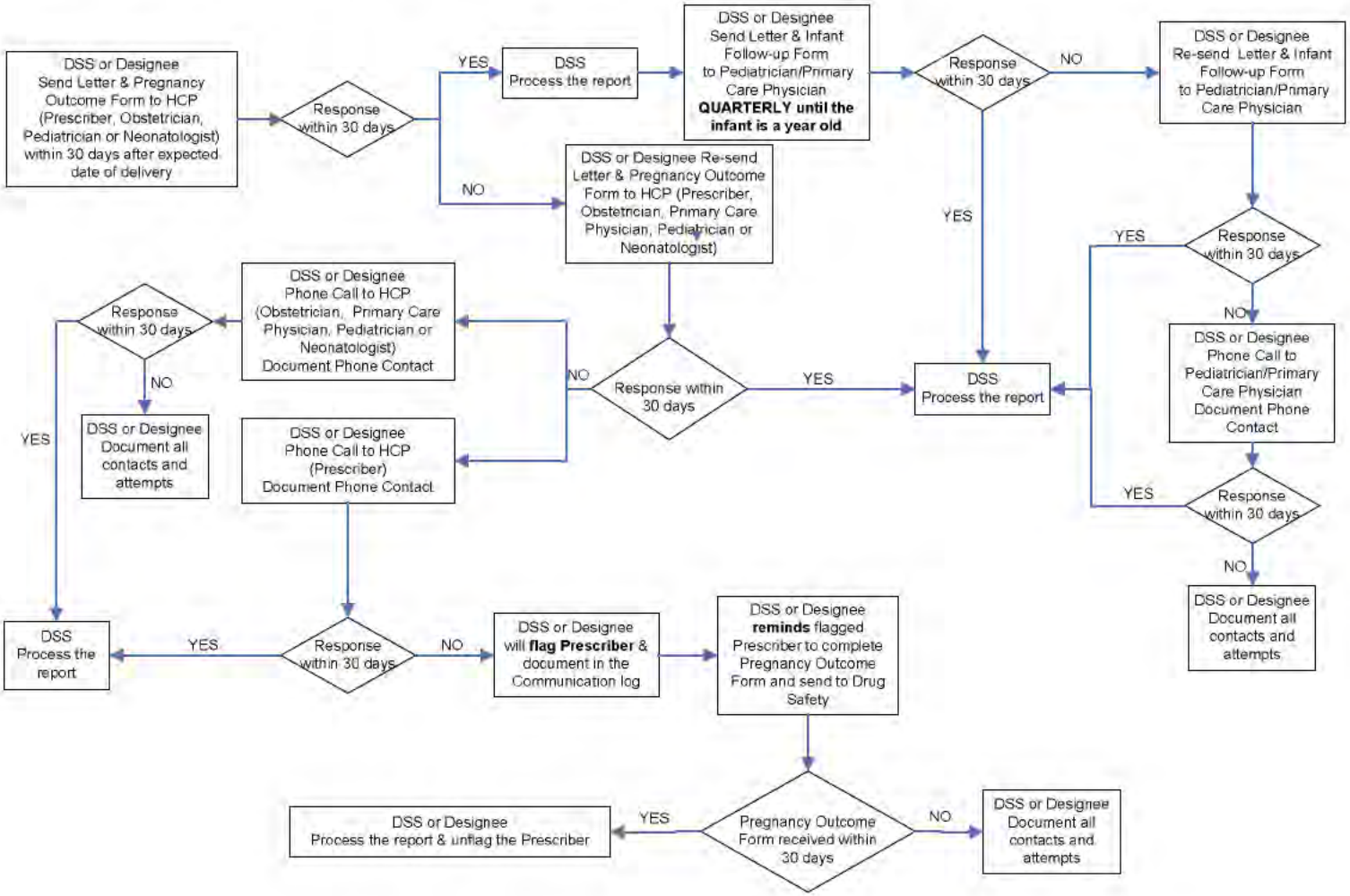
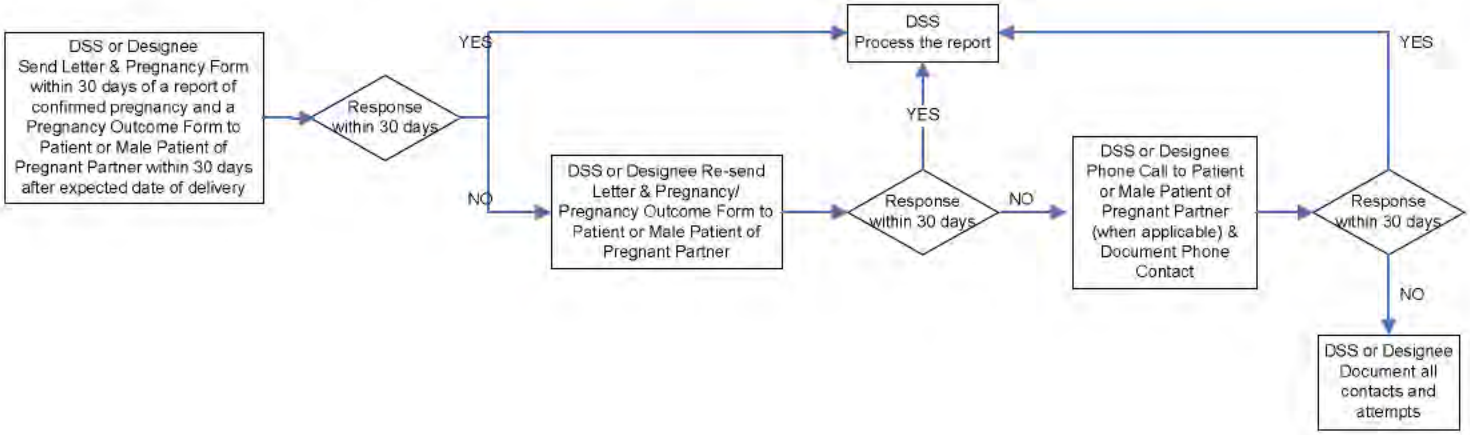


Figure 3: Pregnancy/Pregnancy Outcome Process Flow -Patient and Male Patient of Pregnant Partner



APPENDIX 1: PREGNANCY LETTERS AND QUESTIONNAIRES

Name, MD [Prescriber/Clinical Investigator/Obstetrician/Pediatrician/Neonatologist/Primary Care Physician)
Attn: Name
Address:

DDMMYYYY

Re: Patient Identifier: [patient identifier]
Patient DOB, Patient sex
Drug: [Primary Suspect Product Name]
Our Manufacturer Control No (MCN): [MCN]

Dear Dr. [Selected Reporter]

The Celgene Corporation Global Drug Safety Department has received a report of a pregnancy regarding your patient [patient identifier].

Celgene is committed to investigating any reports of possible embryo-fetal exposure to our products whether it be the patient or patient's partner. In order to perform a thorough evaluation and to meet our regulatory reporting requirements throughout the world, we are interested in obtaining additional details regarding this patient. Please be assured that all information will be treated in the strictest of confidence.

Please complete the enclosed Event-Specific Questionnaire for HCP – Pregnancy Background (Patient or Partner of Patient)/ Event-Specific Questionnaire for HCP - Pregnancy Outcome (Patient or Partner of Patient)/ Event-Specific Questionnaire for HCP - Pregnancy Follow-up (Patient or Partner of Patient)/ Event-Specific Questionnaire for Primary Care Physician or Pediatrician Infant Follow-up Form, date and sign the form(s) and return to Celgene Drug Safety via mail (self-addressed envelope provided), or FAX to (908) 673-9115. Please provide our Manufacturer Control No. as stated above in all communications regarding this case.

If you are aware that further information will not be available, it would be helpful if you could indicate that to us, including the reason if complete information cannot be provided.

If you have any questions, please do not hesitate to contact me at 1-800-640-7854.

Thank you in advance for your assistance.

Name of Specialist
Title

Name of Patient
Address:

DDMMYYYY

Re: Patient Identifier: [patient identifier]
Patient DOB, Patient sex
Drug: [Primary Suspect Product Name]
Our Manufacturer Control No (MCN): [MCN]

Dear [Patient's Name]

The Celgene Corporation Global Drug Safety Department has received a report of your [your partner's pregnancy].

Celgene is committed to investigating any reports of possible embryo-fetal exposure to our products whether it be the patient or patient's partner. In order to perform a thorough evaluation and to meet our regulatory reporting requirements throughout the world, we are interested in obtaining additional details regarding your [your partner's] pregnancy. Please be assured that all information will be treated in the strictest of confidence.

Please complete the enclosed Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner – Pregnancy Background/ Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner – Pregnancy Outcome Form and return to Celgene Drug Safety via mail (self-addressed envelope provided), or FAX to (908) 673-9115.

If you have any questions, please do not hesitate to contact me at 1-800-640-7854.

Thank you in advance for your assistance.

Name of Specialist
Title

Event-Specific Questionnaire for HCP – Pregnancy Background
(Patient or Partner of Patient)
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Drugsafety@celgene.com

Reporter Information				
REPORTER NAME:				
ADDRESS:		CITY, STATE, ZIP, COUNTRY:		
PHONE NO.:		FAX NO.:		
Obstetrician Information (Please provide)				
OBSTETRICIAN NAME:				
ADDRESS:		CITY, STATE, ZIP, COUNTRY:		
PHONE NO.:		FAX NO.:		
Patient Information				
PATIENT ID:	DATE OF BIRTH:	ETHNICITY: ☐ WHITE ☐ AFRICAN-AMERICAN ☐ ASIAN ☐ OTHER, SPECIFY:		
Partner of Patient Information ☐ Not applicable				
DATE OF BIRTH:	ETHNICITY: ☐ WHITE ☐ AFRICAN-AMERICAN ☐ ASIAN ☐ OTHER, SPECIFY:			
Patient Treatment Information: REVLIMID®				
LOT NO.	EXPIRY DATE:	DOSE:	FREQUENCY:	ROUTE:
START DATE		STOP DATE		
INDICATION FOR USE				
CYTOGENETIC ABNORMALITIES: ☐ NO ☐ YES, IF YES, SPECIFY:				

Current Pregnancy					
Date of last menstrual period:		Estimated Delivery Date:			
Pregnancy Test	*REFERENCE RANGE*	*DATE*			
Urine Qualitative					
Serum quantitative					

Prenatal Tests		
	Date	*Result*
Ultrasound		
Ultrasound		
Ultrasound		
Amniocentesis		
Maternal Serum AFP		

Pregnancy History		
No. of previous pregnancies: Date of last pregnancy:	No. of Full term deliveries:	No. of Pre-term births:
No. of fetal deaths:	No. of living children:	No. of abortions: Elective Spontaneous
Type of delivery: Vaginal:	C-section:	Other:, specify
Did birth defect occur in any previous pregnancy? ☐ No ☐ Yes ☐ Unknown If Yes, specify		

MCN:

Pregnancy History

Did a stillbirth or miscarriage occur in any previous pregnancy? ☐No ☐Yes ☐Unknown

1) If Yes, in what week of pregnancy did the stillbirth or miscarriage occur? _____ week

2) Was there any birth defect noted? Specify:

Relevant Medical History

	Date of Diagnosis		*Date of Diagnosis*
Cancer ☐ No ☐ Yes, if yes, specify			

Social History

Alcohol ☐ No ☐ Yes, if yes, amount/unit consumed per day:

Tobacco ☐ No ☐ Yes | IV or recreational drug use ☐ No ☐ Yes, specify

Family History: Congenital Abnormalities ☐ No ☐ Yes, specify:

Medications/Treatments (including herbal, alternative and over the counter medicines and dietary supplements) During Pregnancy

Drug	*Start Date*	*Stop Date/ Continuing*	*Indication*

Adverse Event(s) During Pregnancy

Event(s)	Serious		Serious Criteria[1]	Start Date	Stop Date	Causal Relationship to Celgene Product		
	No	Yes				Yes	No	If No, what medications, disease states etc played a role in the event.

[1] Serious Criteria: **1**) death, **2**) life-threatening, **3**) required inpatient hospitalization or prolongation of existing hospitalization, **4**) a persistent or significant disability/incapacity, **5**) a congenital anomaly/birth defect, **6**) medically significant

Signature of Person Completing this form ..... **Date** .....

MCN:

Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner–
Pregnancy Background
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Drugsafety@celgene.com

Date _____
Name of Patient or Name of Male Patient of Partner _____

For a better understanding of pregnancy among patients or partners of patients on REVLIMID® and for further improvement of the REVLIMID REMS™ program, please complete the following questions.

1. What forms of birth control have you been using while on REVLIMID before you/your partner got pregnant? Please check all that applies.
   - ☐ IUD
   - ☐ Hormonal (birth control pills, hormonal patches, injections, implants)
   - ☐ Tubal ligation
   - ☐ Partner's vasectomy
   - ☐ Latex condom
   - ☐ Diaphragm
   - ☐ Cervical cap or shield
   - ☐ Spermicide or sponge
   - ☐ Withdrawal

2. Were you or your partner at any time during use of REVLIMID without contraception for even one day?
   - ☐ No, please proceed to Q5
   - ☐ Yes, please answer Q3, Q4, Q5, and Q6

3. How often did you have unprotected sexual intercourse?
   - ☐ multiple times
   - ☐ once a week
   - ☐ once every 2 weeks
   - ☐ once a month
   - ☐ not at all
   - ☐ other, specify _____

4. Why did you or your partner interrupt or stop using contraception?
   - ☐ wanted a child
   - ☐ partner disapproved
   - ☐ side effects
   - ☐ health concerns
   - ☐ inconvenient to use
   - ☐ other, specify _____

5. Did you receive the REVLIMID Medication Guide?
   - ☐ No, please proceed to Q6
   - ☐ Yes, please answer the following question

   5.1 Did you read the REVLIMID Medication Guide?
   - ☐ No, please proceed to Q6
   - ☐ Yes, please answer the following question

   5.2 Did you understand the information in the REVLIMID Medication Guide?
   - ☐ No
   - ☐ Yes

6. Where did most of your knowledge about contraception during REVLIMID® use come from?
   - ☐ Physician who prescribed REVLIMID
   - ☐ REVLIMID REMS™ Information booklet
   - ☐ REVLIMID Medication Guide
   - ☐ Other, specify _____

7. Do you feel you and/or your partner had good understanding of the risk of pregnancy during REVLIMID use?
   - ☐ Yes
   - ☐ No
   - ☐ Don't know

Event-Specific Questionnaire for HCP – Pregnancy Follow-up
(Patient or Partner of Patient)
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Drugsafety@celgene.com

Date:	**Period Covered: [Date] to [Date]**
Reporter Information	
REPORTER NAME:	
ADDRESS:	CITY, STATE, ZIP, COUNTRY:
PHONE NO.:	FAX NO.:
Name of Patient or Pregnant Partner of Male Patient	
Current Pregnancy	
Prenatal Tests	

	Date	*Result*
Ultrasound		
Ultrasound		
Ultrasound		
Amniocentesis		
Maternal Serum AFP		
Other tests, specify		

Medications/Treatments (including herbal, alternative and over the counter medicines and dietary supplements) During Pregnancy

DRUG	*START DATE*	*STOP DATE/ CONTINUING*	*INDICATION*

Adverse Event(s) During Pregnancy

Event(s)	SERIOUS		SERIOUS CRITERIA[1]	START DATE	STOP DATE	CAUSAL RELATIONSH P TO CELGENE PRODUCT		
	NO	YES				YES	NO	If No, what medications, disease states etc played a role in the event.

[1] Serious Criteria: **1**) death, **2**) life-threatening, **3**) required inpatient hospitalization or prolongation of existing hospitalization, **4**) a persistent or significant disability/incapacity, **5**) a congenital anomaly/birth defect, **6**) medically significant

SIGNATURE OF PERSON COMPLETING THIS FORM ..... **DATE** .....

MCN:

Event-Specific Questionnaire for HCP – Pregnancy Outcome
(Patient or Partner of Patient)
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Drugsafety@celgene.com

Reporter Information					
REPORTER NAME:					
ADDRESS:				CITY, STATE, ZIP, COUNTRY:	
PHONE NO.:				FAX NO.:	
Patient Information					
PATIENT ID:	DATE OF BIRTH:		ETHNICITY: ☐ WHITE ☐ AFRICAN-AMERICAN ☐ OTHER, SPECIFY:		
Partner of Patient Information ☐ Not applicable					
DATE OF BIRTH:			ETHNICITY: ☐ WHITE ☐ AFRICAN-AMERICAN ☐ OTHER, SPECIFY:		
Pregnancy Outcome					
DATE OF DELIVERY:				GESTATION AGE AT DELIVERY:	
		No	**Yes**		
Normal		☐	☐		
C-section		☐	☐		
Induced		☐	☐		
Ectopic pregnancy		☐	☐		
Elective termination		☐	☐	Date:	
Spontaneous abortion (≤20 weeks)		☐	☐	Weeks from LMP:	
Fetal death/stillbirth (>20 weeks)		☐	☐		
Were the products of conception examined?		☐	☐	If yes, was the fetus normal? ☐ Yes ☐ No ☐ Unknown If no, describe:	
Obstetrics Information					
		No	**Yes**		
Complications during pregnancy		☐	☐	If yes, please specify	
Complications during labor/delivery		☐	☐	If yes, please specify	
Post-partum maternal complications		☐	☐	If yes, please specify	
Fetal Outcome					
		No	**Yes**		
LIVE NORMAL INFANT		☐	☐		
FETAL DISTRESS		☐	☐		
INTRA-UTERINE GROWTH RETARDATION		☐	☐		
NEONATAL COMPLICATIONS		☐	☐	IF YES, PLEASE SPECIFY:	
BIRTH DEFECT NOTED?		☐	☐	IF YES, PLEASE SPECIFY:	
Sex: ☐ Male ☐ Female		**Birth Weight:** __lbs _ oz. or __ kg		**Length:** _____inches or ___ cm.	
Apgar Score:	Unknown:	1 min:	5 min:	10 min:	

SIGNATURE OF PERSON COMPLETING THIS FORM **DATE**

MCN:

Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner–
Pregnancy Outcome
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Drugsafety@celgene.com

Date _____
Name of Patient or Name of Male Patient of Partner _____

Please provide the outcome of your or your partner's pregnancy.

☐ Normal baby

☐ Abnormal baby, please specify defect_____

☐ Therapeutic abortion
Please specify any abnormality of the fetus if known: _____

☐ Spontaneous abortion or miscarriage
Please specify any abnormality of the fetus if known: _____

Event-Specific Questionnaire for Primary Care Physician or Pediatrician – Infant Follow-up

Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Drugsafety@celgene.com

Date: _____
Name of Patient or Name of Male Patient of Partner (Mother)_____
Name of Infant (if known) _____

Please provide information for the period from [**Date]** to [**Date**].

Anomalies Diagnosed Since Initial Report:

_____

☐ None

Developmental Assessment:

☐ Normal

☐ Abnormal, specify _____

Infant Illnesses, Hospitalizations, Drug Therapies:

Infant Illnesses	**Hospitalized?**	**Drug Therapies**
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	

SIGNATURE OF PERSON COMPLETING THIS FORM **DATE**

APPENDIX 2: DEFINITIONS

Fetus: covers the whole prenatal development from the conception until birth.

Pregnancy outcome: the end products of pregnancy which include three main categories: fetal death, termination of pregnancy and live birth.

- Fetal death (intrauterine death, in utero death): death prior to complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the fetus does not show any evidence of life (WHO ICD 10).
    - Early fetal death (before 20 completed weeks of gestation) comprises ectopic pregnancy and miscarriage
    - Late fetal death (after 20 completed weeks of gestation) – known as stillbirth

Miscarriage: spontaneous abortion, molar pregnancy

Termination of pregnancy (induced abortion, elective abortion): artificial interruption of pregnancy

Live birth: the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy, which, after such separation, breathes or shows any evidence of life (WHO ICD 10)

Gestational age or length: duration of gestation is measured from the first day of the last normal menstrual period. Gestation age is expressed in completed days or completed weeks (e.g., events occurring 280 to 286 days after the onset of the last menstrual period are considered to have occurred at 40 weeks of gestation).

Last menstrual period (LMP): according to international consensus, the gestational age is measured from the first day of the LMP.

Birth weight: the initial weight of the infant at birth

Pre-term baby (previously premature birth): less than 37 completed weeks (less than 259 days) of gestation

Term birth: from 37 to less than 42 completed weeks (259 to 293 days)

Post-term birth: 42 completed weeks or more (294 days or more)

Low birth weight: less than 2,500 gram (up to and including 2,499 g) of body weight of the newborn at birth

Intrauterine growth retardation (small for gestational age): the observed weight of a live born infant or size of a fetus is lower than expected on the basis of gestational age.

REMS Patient Survey Reminder

Patient Name_____ **Date Survey Available**_____

Doctor Office Contact and Phone #_____

Product_____ **Pharmacy Name**_____

Telephone Survey

OR

Website Survey

From a touchtone phone dial
1-888-423-5436

Press 2
Para espanol, oprime el numero dos

Press 1
to identify that you are a patient

Press 1
to take a survey

Enter your 9-digit patient identification number (the number you provided during the enrollment process – for example your Social Security Number).

From the menu provided, select the drug that you have been prescribed.

Press 1 OR **Press 2** OR **Press 3**

Your survey will then begin. Please answer all of the questions. Confirmation that the survey has been completed will be provided at the end of your survey.

Access the internet and type in the website address
www.CelgeneRiskManagement.com

You are not required to have a User Name or Password to complete a survey. To take your survey, left click your mouse on the button

Patient Surveys

You will be asked for the following information. Please enter the information exactly as it was provided during your enrollment process

After entering the information above, click

Start Survey

Survey questions will be displayed 1 per page. Please be sure to complete the survey in its entirety. A summary page displaying your survey answers will be displayed at the end of your survey. Upon completion, send the survey to Celgene by clicking

Send to Celgene

REMS-GEN12169
Reference ID: 3319577

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety kit

RevlimidREMS™ REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety kit

Risks of REVLIMID® (lenalidomide)

- REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or embryo-fetal death. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

REVLIMID in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Revlimid® (lenalidomide) capsules

Reference ID: 3319577

Reference ID: 3319577

RevlimidREMS™

Prescriber quick reference guide

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes REVLIMID® (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
   - Visiting **www.CelgeneRiskManagement.com**, or
   - Calling Celgene Customer Care Center at **1-888-423-5436**

   Male patients do not need to complete the initial survey.

   All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to REVLIMID REMS™ Program (formerly known as the RevAssist® program).
5. The prescriber completes mandatory confidential survey and receives authorization number by:
   - Visiting **www.CelgeneRiskManagement.com**, or
   - Calling Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes REVLIMID prescription and includes authorization number and patient risk category.
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the REVLIMID REMS™ procedures.

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

Celgene

RevlimidREMS™

Revlimid® (lenalidomide) capsules

Patient Guide to

Revlimid REMS™

Risk Evaluation and Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of REVLIMID® (lenalidomide)
  - Birth defects (deformed babies) or death of an unborn baby
  - Low white blood cells (neutropenia) and low platelets (thrombocytopenia)
  - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
- The REVLIMID REMS™ program
  - What females who can get pregnant need to know
    - Birth control options
  - What females who can not get pregnant need to know
  - What males need to know

Revlimid® (lenalidomide) capsules

Reference ID: 3319577

Table of contents

Risks of REVLIMID® (lenalidomide)

REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or death to unborn babies. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

What is the REVLIMID REMS™ program?

To avoid serious risks to unborn babies, REVLIMID is only available under a restricted distribution program called the "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™" (formerly known as the RevAssist® program). Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID. In order to receive REVLIMID, patients must be enrolled in the REVLIMID REMS™ program and agree to follow the requirements.

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center toll-free at **1-888-423-5436.**

What do all patients need to know about the REVLIMID REMS™ program?

General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects
- REVLIMID® (lenalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle REVLIMID capsules
- Keep REVLIMID in a cool, dry place
- Do **not** donate blood while you are taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID
- Unused REVLIMID capsules should be returned for disposal to Celgene by calling **1-888-423-5436**, or to your REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to you

What do females who can get pregnant need to know about the REVLIMID REMS™ program?

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says you understand that REVLIMID should not be used during pregnancy, and that you agree not to become pregnant while taking REVLIMID
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking REVLIMID
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for REVLIMID, and again within 24 hours before you receive your first prescription for REVLIMID. If you are pregnant, you cannot take REVLIMID
- You will have pregnancy tests before starting REVLIMID and while taking REVLIMID, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for REVLIMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies

- Before dispensing REVLIMID® (lenalidomide), your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options

1. **Choose at least 1 highly effective method and at least 1 additional effective method of birth control.** Talk to your healthcare provider about the following acceptable birth control methods. See below.

Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Male latex or synthetic condom + Diaphragm Cervical cap

2. **Use the 2 methods of birth control at the same time**

- **Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

What do females who can get pregnant need to know about the REVLIMID REMS™ program? (continued)

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective**

3. Unacceptable methods of birth control

- Progesterone-only "mini-pills"
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for REVLIMID® (lenalidomide) and again within 24 hours before receiving your first prescription for REVLIMID. Both pregnancy tests must have a negative result

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

B. While taking REVLIMID® (lenalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider:
  - Every week during the first 4 weeks of treatment, then
  - Every 4 weeks if your menstrual cycles are regular, or
  - Every 2 weeks if your cycles are irregular
  - If you miss your period or have unusual menstrual bleeding, or
  - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking REVLIMID immediately and call your healthcare provider right away

What do females who can get pregnant need to know about the REVLIMID REMS™ program? (continued)

- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking REVLIMID® (lenalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking REVLIMID
- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking REVLIMID® (lenalidomide)

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
  - For at least 4 weeks after stopping REVLIMID, or
  - Do not have any sex with a male for 4 weeks after stopping REVLIMID

See also “General guidelines” on page 5 for requirements for all patients.

What do females who can not get pregnant need to know about the REVLIMID REMS™ program?

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
  - You have been in natural menopause for at least 2 years, or
  - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting REVLIMID
- Before your healthcare provider can write your prescription for REVLIMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing REVLIMID® (lenalidomide), your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking REVLIMID

- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

See also “General guidelines” on page 5 for requirements for all patients.

What do males need to know about the REVLIMID REMS™ program?

- You must use a latex or synthetic condom, **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form. You must agree that while taking REVLIMID you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing REVLIMID, your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking REVLIMID

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must **not** donate sperm while taking REVLIMID® (lenalidomide) (including during breaks [dose interruptions])
- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking REVLIMID

- For 4 weeks after receiving your last dose of REVLIMID, you must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping REVLIMID

See also “General guidelines” on page 5 for requirements for all patients.

Mandatory confidential patient surveys

As a patient who is enrolled in the REVLIMID REMS™ program for REVLIMID® (lenalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

Female children

- Initial survey before first prescription
- Monthly

Males

- No initial survey
- Monthly

Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of **www.CelgeneRiskManagement.com,** or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a REVLIMID REMS™ certified pharmacy. The REVLIMID REMS™ certified pharmacy will contact you to discuss your REVLIMID® (lenalidomide) therapy. You will not receive your medication until you speak with the REVLIMID REMS™ certified pharmacy
- For more information, contact the Celgene Customer Care Center at **1-888-423-5436**

Warning to patients taking REVLIMID® (lenalidomide)

Attention females:

Do **not** take REVLIMID if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID.

Attention all patients:

You must **not** donate blood while taking REVLIMID® (lenalidomide), during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects.

REVLIMID must be kept out of the reach of children. Return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**, or to your REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to you.

You may require regular blood tests during REVLIMID treatment. Consult with your healthcare provider.

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

RevlimidREMS™

1/13

REMS-REV12103

Reference ID: 3319577

RevlimidREMS™

At-A-Glance

Important information about REVLIMID® (lenalidomide) and the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program

- REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™" (formerly known as the RevAssist® program)
- Only prescribers and pharmacies certified by the REVLIMID REMS™ program can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMS™ program
- Information about REVLIMID and the REVLIMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com,** or call the Celgene Customer Care Center at **1-888-423-5436**.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

Celgene

RevlimidREMS™

Revlimid® (lenalidomide) capsules

Reference ID: 3319577

Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for REVLIMID® (lenalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open REVLIMID capsules.
3. Obtain, review, and complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
   - **Males (adults and children)**
   - **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
   - **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
4. Send the completed and signed REVLIMID® (lenalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
   - Males do not need to complete the initial survey
6. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
   - You will need to enter the following information:
     - Prescriber's identification number
     - Patient's identification number
     - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
     - Average daily dose
     - Total number of days supplied (cannot exceed 28 days)
7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
8. Send the prescription to a certified pharmacy.

Subsequent prescriptions (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open REVLIMID capsules.
3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
   - Monthly:
     - **Males (adults and children)**
     - **Females of reproductive potential (adults and children)**
     - **Female children not of reproductive potential**
   - Every 6 months:
     - **Adult females not of reproductive potential**
4. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.
   - You will need to enter the following information:
     - Prescriber's identification number
     - Patient's identification number
     - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
     - Average daily dose
     - Total number of days supplied (cannot exceed 28 days)
5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
6. Send the prescription to a certified pharmacy.

Celgene REMS Programs Pharmacy Training: REVLIMID REMS™

Section 1: What Is a REMS?

In this section

- What is a REMS?
- Celgene REMS programs
- Pharmacy staff knowledge check

What is a REMS?

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- REMS programs are mandated by the **US Food and Drug Administration (FDA)**
- According to the FDA, a REMS program is:
  - A strategy to manage a known or potential serious risk associated with a drug or biological product
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

Celgene REMS programs

- Celgene has REMS programs for THALOMID® (thalidomide), REVLIMID® (lenalidomide), and POMALYST® (pomalidomide):
  - THALOMID REMS™ program (formerly known as the *S.T.E.P.S.*® program) for THALOMID
  - REVLIMID REMS™ program (formerly known as the RevAssist® program) for REVLIMID
  - POMALYST REMS™ for POMALYST
- If these treatments are used during pregnancy, they can cause serious birth defects or embryo-fetal death
- The goals of these REMS programs are:
  - To prevent the risk of embryo-fetal exposure to these treatments
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

Celgene REMS programs (continued)

For more information on Celgene REMS programs:

- Call Celgene Customer Care at 1-888-423-5436
- Visit the specific product website

Did you know?

Celgene Customer Care has Compliance Specialists to educate and train pharmacy staff on Celgene REMS program guidelines and compliance.

Reference ID: 3319577

Pharmacy staff knowledge check

- REMS stands for Risk Evaluation and Mitigation Strategies.
  - A. True
  - B. False

Correct Answer: A. True

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product

Pharmacy staff knowledge check (continued)

- Who mandates REMS programs?
  - A. Celgene
  - B. The FDA
  - C. The EPA

Correct Answer: B. The FDA

- REMS programs are mandated by the FDA
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

Pharmacy staff knowledge check (continued)

- Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment.
  - A. True
  - B. False

Correct Answer: A. True

- The goals of the Celgene REMS programs are:
  - To prevent the risk of embryo-fetal exposure to these treatments
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

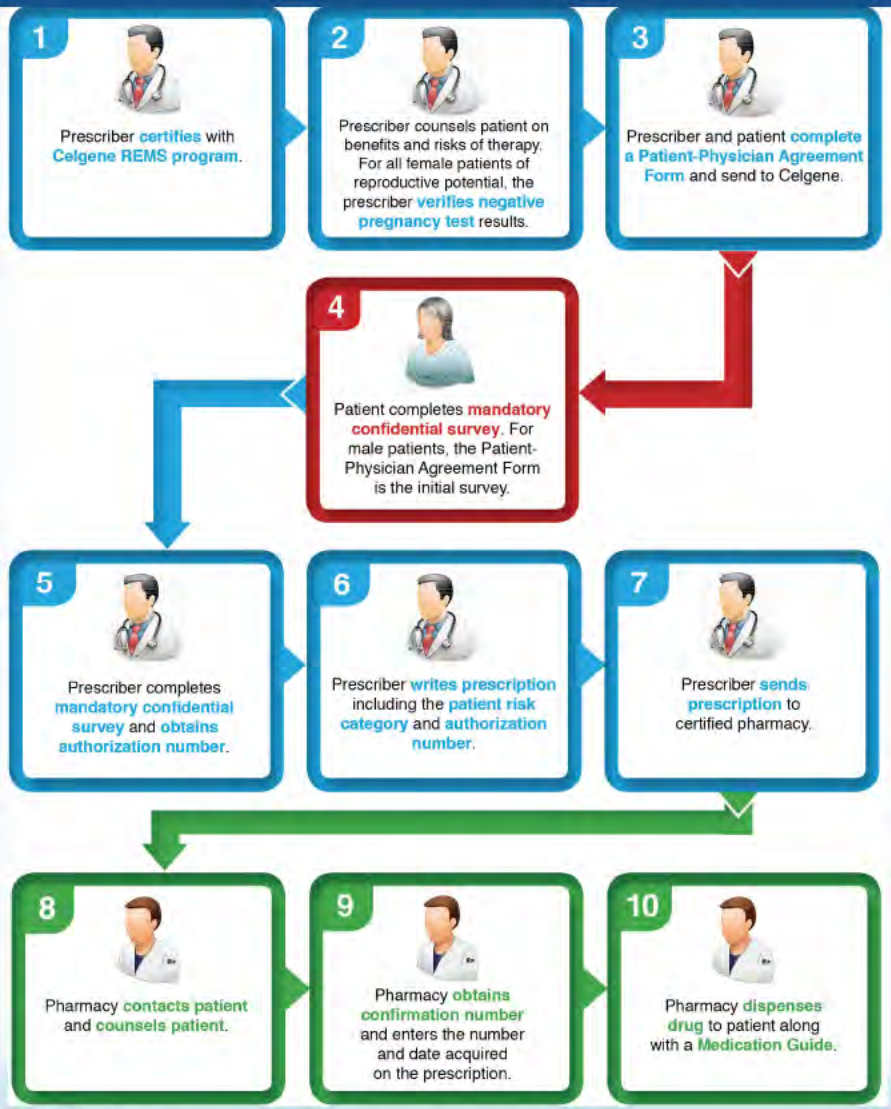
Celgene REMS Programs Pharmacy Training: REVLIMID REMS™

Section 2: Program Requirements for Patients and Prescribers

In this section

- Program overview
- Certification and enrollment requirements for prescribers and patients
- Patient risk categories
- Contraception requirements
- Pregnancy test requirements
- Mandatory confidential surveys
- Pharmacy staff knowledge check

Celgene REMS program overview



Reference ID: 3319577

Certification and enrollment requirements for prescribers and patients

- Prescribers must be certified with the Celgene REMS program in order to prescribe a product with a REMS program for a patient
    - Prescribers must complete the REMS program enrollment and agree to comply with the program requirements
- Prescribers are required to enroll patients in a specific Celgene REMS program before starting a patient on a therapy with a REMS
    - Patients must enroll in the REMS program and agree to comply with the program requirements

Patient risk categories

- There are 6 different patient risk categories for patients enrolled in Celgene REMS programs:
  - Adult female of reproductive potential
  - Female child of reproductive potential
  - Adult female not of reproductive potential
  - Female child not of reproductive potential
  - Adult male
  - Male child

Definition of females of reproductive potential

Females of reproductive potential include all females who:

- Are menstruating
- Are amenorrheic from previous medical treatments
- Are under 50 years of age
- Are perimenopausal
- Do not qualify for the females not of reproductive potential category

The risk categories for **females of reproductive potential** are:

- Adult female of reproductive potential
- Female child of reproductive potential

Definition of females not of reproductive potential

Females not of reproductive potential include females who:

- Have been in natural menopause for at least 24 consecutive months
- Have had a hysterectomy and/or bilateral oophorectomy
- Have not started menstruating

The risk categories for **females not of reproductive potential** are:

- Adult female not of reproductive potential
- Female child not of reproductive potential

Definition of males

Males include adults and children (under 18 years of age)

The risk categories for **males** are:

- Adult Male
- Male Child

Contraception requirements: Females of reproductive potential

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time **at least 1 highly effective method** and **at least 1 additional method** of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Highly effective methods
Tubal ligation
Intrauterine device (IUD)
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)
Partner's vasectomy
Additional effective methods
Male latex or synthetic condom
Diaphragm
Cervical cap

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

Contraception requirements: Females of reproductive potential (continued)

- **Unacceptable contraception methods**:
  - Progesterone-only "mini-pills"
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield
    - A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

Contraception requirements: Males

- Male patients must use a latex or synthetic condom:
  - Every time they have sexual intercourse with a female of reproductive potential
  - Even if they have undergone a successful vasectomy
  - During therapy (including dose interruptions)
  - For 4 weeks after discontinuation of therapy

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

Pregnancy test requirements

- For females of reproductive potential, prescriber must obtain a negative pregnancy test:
  - 10 to 14 days before an initial prescription
  - Within 24 hours before an initial prescription
  - The pregnancy test must be sensitive to at least 50 mIU/mL
- Subsequent pregnancy testing should occur:
  - Weekly during the first 4 weeks of use, then
  - Every 4 weeks if patient has regular menses or no menses, or
  - Every 2 weeks if irregular menses

Pregnancy test requirements (continued)

If pregnancy does occur:

- Treatment must be **immediately** discontinued
- Any suspected embryo-fetal exposure must be reported **immediately** to Celgene Global Drug Safety and reported to the FDA
  - Celgene Global Drug Safety: 1-800-640-7854
  - FDA MedWatch number: 1-800-332-1088
- The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

Mandatory confidential surveys

- All patients must complete brief mandatory confidential surveys in order to obtain treatment
  - Surveys can be completed via CelgeneRiskManagement.com or by calling Celgene Customer Care at 1-888-423-5436

Patient Mandatory Confidential Survey Schedule for Adults and Children		
Risk category	**Initial Prescription**	**Subsequent Prescriptions**
Females of reproductive potential	Complete appropriate survey	Monthly survey
Females not of reproductive potential	Complete appropriate survey	Child: Monthly survey Adult: Survey every 6 months
Males	Do not need to take initial survey	Monthly survey

Pharmacy staff knowledge check

- How many patient risk categories are there in the Celgene REMS programs?
  - A. 3
  - B. 5
  - C. 6

Correct Answer: C. 6

Celgene REMS program patient risk categories	
Adult	**Child (under 18)**
Adult female of reproductive potential	Female child of reproductive potential
Adult female not of reproductive potential	Female child not of reproductive potential
Adult male	Male child

Pharmacy staff knowledge check (continued)

- For all Celgene REMS products, female patients of reproductive potential must take a pregnancy test:
  - A. 10-14 days before first prescription
  - B. Within 24 hours before first prescription
  - C. 10-14 days and within 24 hours before first prescription

Correct Answer:
C. 10-14 days and within 24 hours before first prescription

- Prescribers must obtain 2 negative pregnancy tests before the first prescription for females of reproductive potential:
  - 10 to 14 days before an initial prescription
  - Within 24 hours before an initial prescription

Pharmacy staff knowledge check (continued)

- Which is a **highly effective** method of contraception?
  - A. Male latex or synthetic condom
  - B. IUD
  - C. Female condom

Correct Answer: B. IUD

Highly effective methods	Additional effective methods
Tubal ligation	Male latex or synthetic condom
Intrauterine device (IUD)	Diaphragm
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Cervical cap
Partner's vasectomy	

Celgene REMS Programs Pharmacy Training: REVLIMID REMS™

Section 3: Program Requirements for Pharmacies

In this section

- Training and certification requirements
- Pharmacy compliance
- Pharmacy staff knowledge check

Training and certification requirements

- Celgene REMS program certified counselors must:
  - Be licensed healthcare professionals
  - Complete the Celgene-sponsored training on all required modules **annually** and pass certification exam **with 100% accuracy**
  - Educate patient by telephone or in person before treatment can be dispensed
  - Understand and counsel patients on the potential for birth defects or death to an unborn baby
  - Counsel patients on possible side effects
- Other pharmacy staff involved in dispensing treatment must:
  - Be educated on the guidelines for dispensing

Pharmacy compliance

- Pharmacy manager responsibilities
  - Educate all staff regarding dispensing guidelines
    - Includes floater pharmacists, pharmacy technicians, or anyone else handling the product
  - Make sure counselors are registered and certified in ComplianceWire® and advise Celgene of inactive counselors
  - Complete and return all documentation that pertains to non-compliance

Did you know? Pharmacy managers can call Celgene Customer Care at **1-888-423-5436** with questions. Ask for Risk Compliance.

Pharmacy compliance (continued)

- Pharmacy deviations
  - The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
  - Celgene will work with the pharmacy to implement appropriate corrective actions and a timeframe for those actions
  - If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

Pharmacy compliance (continued)

- A High Risk Deviation is:
  - Any action taken by the pharmacy that is inconsistent or non-compliant with the Celgene REMS program that increases the risk of embryo-fetal exposure
  - Any action that occurs on a consistent basis that shows a pharmacy's negligent or willful disregard to the Celgene REMS program requirements
- If there are 3 High Risk Deviations within 1 year, the pharmacy will be deactivated and will no longer be permitted to dispense product

Pharmacy staff knowledge check

- Celgene REMS program certified counselors must complete the Celgene-sponsored training:
  - A. Annually
  - B. Every 6 months
  - C. Every 2 years

Correct Answer: A. Annually

- Counselors must complete the Celgene-sponsored training annually

Pharmacy staff knowledge check (continued)

- All counselors must pass the certification test with an accuracy of:
  - A. 100%
  - B. 90%
  - C. 95%

Correct Answer: A. 100%

- Counselors must pass the certification exam with 100% accuracy

Pharmacy staff knowledge check (continued)

- Celgene may deactivate pharmacies for deviations.
  - A. True
  - B. False

Correct Answer: A. True

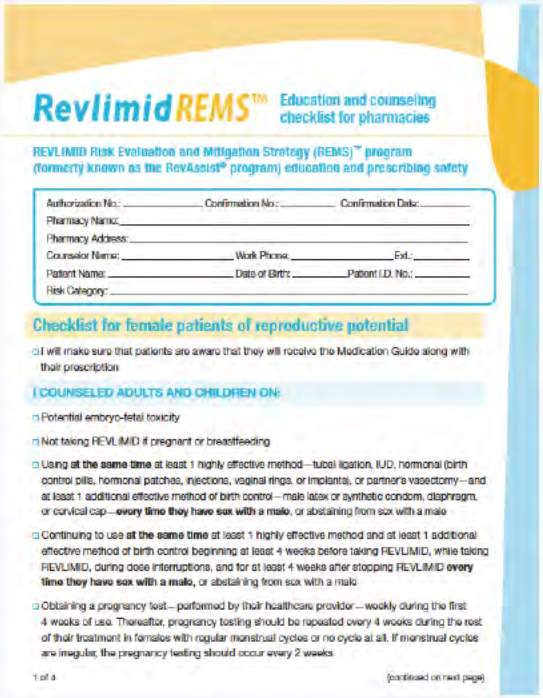
- The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
- If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

Celgene REMS Programs Pharmacy Training: REVLIMID REMS™

Section 4: Guidelines for Counseling

In this section

- Counseling for female patients of reproductive potential
- Counseling for female patients not of reproductive potential
- Counseling for male patients
- Additional counseling for all patients taking REVLIMID® (lenalidomide)
- Pharmacy staff knowledge check



Revlimid REMS™ Education and counseling checklist for pharmacies

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program) education and prescribing safety

Authorization No.: _____ Confirmation No.: _____ Confirmation Date: _____
Pharmacy Name: _____
Pharmacy Address: _____
Counselor Name: _____ Work Phone: _____ Ext.: _____
Patient Name: _____ Date of Birth: _____ Patient I.D. No.: _____
Risk Category: _____

Checklist for female patients of reproductive potential

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

☐ Potential embryo-fetal toxicity

☐ Not taking REVLIMID if pregnant or breastfeeding

☐ Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male

☐ Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking REVLIMID, while taking REVLIMID, during dose interruptions, and for at least 4 weeks after stopping REVLIMID **every time they have sex with a male,** or abstaining from sex with a male

☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks

1 of 4 (continued on next page)

The sequence of this section is based on the Education and Counseling Checklist for Pharmacies.

Remember to fill out this checklist for every patient for every prescription.

Counseling for female patients of reproductive potential

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity
- Not taking treatment if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time they have sex with a male,** or abstaining from sex with a male
  - **Highly effective** methods of contraception: Tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy
  - **Additional effective** methods of contraception: Male latex or synthetic condom, diaphragm, or cervical cap

Counseling for female patients of reproductive potential (continued)

COUNSEL ADULTS AND CHILDREN ON:

- Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
  - Beginning at least 4 weeks before treatment
  - During treatment
  - During dose interruptions
  - For at least 4 weeks after stopping treatment
  - **Every time they have sex with a male**, or abstaining from sex with a male

Counseling for female patients of reproductive potential (continued)

COUNSEL ADULTS AND CHILDREN ON:

- Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use
  - Pregnancy testing should be repeated:
    - Every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all
    - If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- The need to stop treatment right away **in the event of becoming pregnant**, or **if they think for any reason they may be pregnant**, and to call their healthcare provider immediately

Counseling for female patients of reproductive potential (continued)

COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
    - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

Counseling for female patients not of reproductive potential

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
    - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

Counseling for female patients not of reproductive potential (continued)

FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance
- Parent or legal guardian must inform the child's doctor when the child begins menses

Counseling for male patients

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity and contraception
  - Wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant
- Female partners of males receiving treatment must call their healthcare provider right away if they get pregnant

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Counseling for male patients (continued)

COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood or sperm during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
    - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

FOR MALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

Additional counseling for all patients taking REVLIMID® (lenalidomide)

COUNSEL ADULTS AND CHILDREN ON:

- Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- For del 5q MDS patients, the need for weekly blood tests to be completed for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID

Counsel patient to **contact healthcare provider** if experiencing any side effects.

Pharmacy staff knowledge check

- Which of these is **not** something patients need to be counseled on?
  - A. Not sharing capsules
  - B. Not breaking, chewing, or opening capsules
  - C. Wearing gloves while taking capsules

Correct Answer: C. Wearing gloves while taking capsules.

- Patients must be counseled on:
  - Not sharing capsules with anyone—especially with females who can get pregnant
  - Not breaking, chewing, or opening capsules

Pharmacy staff knowledge check (continued)

- Female patients of reproductive potential must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
  - A. True
  - B. False

Correct Answer: A. True

- Female patients of reproductive potential must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
  - Beginning at least 4 weeks before treatment
  - During treatment
  - During dose interruptions
  - For at least 4 weeks after stopping treatment
  - **Every time they have sex with a male**, or abstaining from sex with a male

Pharmacy staff knowledge check (continued)

- All patients must receive a Medication Guide along with their prescription.
  - A. True
  - B. False

Correct Answer: A. True

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

Celgene REMS Programs Pharmacy Training: REVLIMID REMS™

Section 5: Guidelines for Dispensing

In this section

- Pharmacy and prescription requirements
- Dispensing guidelines
- Steps for dispensing
- Pharmacy staff knowledge check

Pharmacy and prescription requirements

- Dispensing pharmacies must be certified in the applicable Celgene REMS program and educated on the program and on dispensing procedures for the treatment
- Pharmacy must ensure that every prescription includes:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature
- Authorization numbers are valid for **7 days** from the date of last pregnancy test for female patients of reproductive potential and **30 days** from the date it is issued for all other patients
- No automatic refills or telephone prescriptions are permitted
- Faxed prescriptions are permissible depending on state laws

Dispensing guidelines

- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide. A new prescription is required for further dispensing
- **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription**
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or picked-up within 24 hours** of obtaining confirmation
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame
    - Pharmacy must obtain a new confirmation number by calling Celgene Customer Care at 1-888-423-5436 when ready to ship or have the product picked-up

Dispensing guidelines (continued)

- When shipping, pharmacy must require a signature confirming receipt
- Pharmacy shall keep an inventory log for the drug, by strength, reflecting its on-hand inventory at all times
- Do not transfer the drug to another pharmacy without prior authorization from Celgene
- Accept unused capsules (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal

Steps for dispensing

Review incoming prescriptions

- Only accept prescriptions with all of the following information:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature
- Make sure the prescription is signed and dated
- Confirm the prescription is written for a 4-week (28-day) supply or less
- For subsequent prescriptions, verify there are 7 days or less of therapy remaining on the existing prescription

Steps for dispensing (continued)

Counsel patient

- Patients must receive counseling from a Celgene REMS program certified pharmacy counselor
- Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist
  - Make sure form is signed and dated by the counselor and appropriate boxes are checked off
  - Keep a copy of the checklist and the associated prescription
- Please report adverse drug experiences that are suspected to be associated with the use of the drug and any suspected pregnancy occurring during the treatment

Steps for dispensing (continued)

Obtain confirmation number from Celgene

- Prior to each prescription, contact Celgene Customer Care at 1-888-423-5436, available 24 hours a day, 7 days a week

1. Enter the pharmacy NABP number or DEA number
2. Enter the authorization number written on the prescription
3. Enter the number of capsules and milligram strength being dispensed
4. Write the **confirmation number** and **date** on the prescription. Note: the confirmation number is **only valid for 24 hours**

- If you do not obtain a confirmation number, you are not permitted to dispense the product to the patient

If you have questions about the validity of the authorization or confirmation numbers, call Celgene Customer Care.

Steps for dispensing (continued)

Dispense prescription

- Include a Medication Guide with each prescription
- Document the dispense date on either the shipping receipt or pharmacy dispensing log
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or handed to the patient within 24 hours**

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Pharmacy staff knowledge check

- A confirmation number is valid for:
  - A. 24 hours
  - B. 7 days
  - C. 30 days

Correct Answer: A. 24 hours

- The confirmation number is **only valid for 24 hours**
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame

Pharmacy staff knowledge check (continued)

- Each prescription must have both an authorization number and a patient risk category written on it.
  - A. True
  - B. False

Correct Answer: A. True

- Only accept prescriptions with all of the following information:
  - Patient and prescriber demographics and contact information
  - Patient risk category
  - Dosing information and instructions
  - Authorization number
  - Prescriber signature

Reference ID: 3319577

Pharmacy staff knowledge check (continued)

- The pharmacy must dispense no more than a 4-week (28-day) supply.
  - A. True
  - B. False

Correct Answer: A. True

- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide
- A new prescription is required for further dispensing

You May Want Emergency Contraception If

- His condom broke or slipped off, and he ejaculated inside your vagina.
- You forgot to take your birth control pills.
- Your diaphragm, cap, or shield slipped out of place, and he ejaculated inside your vagina.
- You miscalculated your "safe" days.
- He didn't pull out in time.
- You weren't using any birth control.
- He forced you to have unprotected vaginal sex.

Contact your health care provider immediately if you have had unprotected intercourse and you think you might become pregnant. **Ask about emergency contraception.**

Planned Parenthood®

www.plannedparenthood.org
www.teenwire.com
Other publications —
www.ppfastore.org

EC — Emergency Contraception
2675 9/08–180 2.13.5
ISBN 1-930996-91-8
Printed in the U.S.A.

How Well Emergency Contraception Works

- **Progestin-only EC reduces the risk of pregnancy by 89 percent if started within 72 hours of unprotected intercourse.** For example, eight out of 100 women will become pregnant after having unprotected sex once during the second or third week of their cycles. But only one woman out of 100 will become pregnant after taking progestin-only EC.
- **Combination EC reduces the risk of pregnancy by 75 percent if started within 72 hours of unprotected intercourse.** Only two women out of 100 will become pregnant after taking combination EC.

Emergency contraception is meant as backup birth control only. EC is not as effective as the correct and consistent use of reversible contraception — the IUD, the shot, the pill, the patch, or the ring.

EC does not continue to prevent pregnancy during the rest of the cycle. Other methods of birth control must be used.

Emergency contraception offers no protection against sexually transmitted infections. You may want to consider testing for sexually transmitted infections if there is a possibility that unprotected sex put you at risk.

How to Get Emergency Contraception

Plan B is now available over the counter for women 18 and older. Plan B and other forms of emergency contraception are also available by prescription for all women. Contact your local Planned Parenthood at 1-800-230-PLAN to get EC or to get a prescription for EC if you are younger than 18. You may also get EC at your local pharmacy if you are older than 18.

If you are younger than 18, you may want to ask your clinician for a prescription for EC before you need it. This will allow you to use EC in emergency situations without having to wait to get an appointment.

Costs Vary Widely

Costs depend on which of the following services are needed. Here are some estimates:

EC	Range of Costs
Plan B	$10 – $60
one pack of combination pills	$20 – $50
visit with health care provider	$35 – $150
pregnancy test	$10 – $20
Range of Total Cost	$10 – $255

Fees may be less at family planning clinics and health centers. Some use a sliding scale based on income. Costs vary from community to community, based on regional and local expenses. Contact your nearest Planned Parenthood health center at 1-800-230-PLAN for information about costs in your area.

Emergency IUD Insertion

IUDs can also be used as backup birth control. A clinician can insert a Copper T 380A IUD (ParaGard®) for emergency contraception within five days of unprotected intercourse. It can be left in place for up to 12 years for very effective contraception. Or the IUD can be removed after your next menstrual period, when it is certain that you are not pregnant. Emergency IUD insertion reduces the risk of pregnancy by 99.9 percent.

For more information about the advantages and disadvantages of the IUD as a regular method of birth control, read the Planned Parenthood pamphlet, *Understanding IUDs.*

Update — Jon Knowles, September 2008
Original version — Jon Knowles, 1996

ISBN 1-930996-91-8

Emergency Contraception

Planned Parenthood®
America's most trusted name in women's health.®

- **EC can prevent pregnancy *after* unprotected vaginal intercourse.** *It is also called "the morning-after pill," emergency birth control, or backup birth control.*
- **EC must be started within 120 hours — five days — after unprotected intercourse.**
- **The sooner it is started, the better.** *EC reduces the risk of pregnancy by 75–89 percent when the first dose is taken within 72 hours.*

EC contains hormones found in birth control pills and prevents pregnancy by stopping ovulation or fertilization. Theoretically, EC could also prevent implantation, but that has not been proven scientifically.

Plan B® is a brand of hormone pills approved by the FDA specifically for emergency contraception. Certain birth control pills may also be prescribed for use as emergency contraception. Some EC regimens use "combination pills" with estrogen and progestin — synthetic hormones like the ones a woman's body makes. Plan B has progestin only.

EC will not cause an abortion or affect an existing pregnancy. Still, a woman should not use emergency contraception if she is pregnant.

How to Use EC

Plan B can be taken in one dose or in two doses, 12 hours apart. Combined hormone pills must be taken in two doses, 12 hours apart. The number of pills in a dose varies with the brand of the pill. Use the same brand for both doses.

Swallow the pill(s) in the first dose as soon as possible, up to 120 hours — five days — after having unprotected sex. EC may cause nausea and vomiting. This risk is much higher for combination pills than for progestin-only pills.

To reduce the risk of nausea, you may want to take an anti-nausea medication, such as Dramamine or Bonine one hour before taking EC.

If you are taking the pills in two doses, swallow the second dose 12 hours after taking the first. If you vomited after the first dose, be sure to use an anti-nausea medication one hour before taking the second dose. Or you may want to take the second dose as a vaginal suppository by inserting the pills with your fingers as high into your vagina as you can reach. (The medication will be absorbed through the vaginal tissue.)

If you vomit the second dose, do not take any extra pills. They probably won't reduce the risk of pregnancy. But they will probably make you sick to your stomach.

Pill Brand	1st Dose (within 120 hours)	2nd Dose (12 hours later)
Plan B	1 white pill	1 white pill*
Alesse	5 pink pills	5 pink pills
Aviane	5 orange pills	5 orange pills
Cryselle	4 white pills	4 white pills
Enpresse	4 orange pills	4 orange pills
Jolessa	4 pink pills	4 pink pills
Lessina	5 pink pills	5 pink pills
Levlen	4 light-orange pills	4 light-orange pills
Levlite	5 pink pills	5 pink pills
Levora	4 white pills	4 white pills
Lo/Ovral	4 white pills	4 white pills
Low-Ogestrel	4 white pills	4 white pills
Lutera	5 white pills	5 white pills
Lybrel	6 yellow pills	6 yellow pills
Nordette	4 light-orange pills	4 light-orange pills
Ogestrel	2 white pills	2 white pills
Ovral	2 white pills	2 white pills
Portia	4 pink pills	4 pink pills
Quasense	4 white pills	4 white pills
Seasonale	4 pink pills	4 pink pills
Seasonique	4 light-blue-green pills	4 light-blue-green pills
Tri-Levlen	4 yellow pills	4 yellow pills
Triphasil	4 yellow pills	4 yellow pills
Trivora	4 pink pills	4 pink pills

*Both doses of Plan B can be taken at the same time.

After You Take the Pills

- Your next period may be earlier or later than usual.
- Your flow may be heavier, lighter, more spotty, or the same as usual.
- Tell any other health care provider you may see before you get your next period that you have taken EC.
- Schedule a follow-up visit with your clinician if you do not have your period in three weeks or if you have symptoms of pregnancy.
- Be sure to use another method of contraception if you have vaginal intercourse any time before you get your period again.
- Continue using the birth control method of your choice for as long as you want to avoid pregnancy.

Side Effects

Side effects associated with the use of EC usually taper off within a day or two.

- Half of the women who take the combination pills feel sick to their stomachs, but only for about 24 hours. Less than one out of five women vomit with combination pills.
- The risk of nausea and vomiting is much lower with progestin-only EC, like Plan B — less than one in four women feel sick to their stomachs.
- Breast tenderness, irregular bleeding, dizziness, and headaches may also occur.

There have been no reports of serious complications among the millions of women who have used EC.

Frequent use of EC may cause periods to become irregular and unpredictable.

The side effects of anti-nausea medication may include drowsiness. Please follow the precautions on the package insert.

continued over →

Prescriber Guide to Revlimid REMS™

Risk Evaluation and Mitigation Strategy (REMS)™ Program

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID® (lenalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program).

This guide contains important information for prescribers about:

- The risks of REVLIMID, including a boxed warning for
  - Embryo-fetal toxicity
  - Hematologic toxicity
  - Deep vein thrombosis
- The REVLIMID REMS™ program
  - Prescriber Certification
  - Patient Enrollment
  - Contraceptive Requirements and Counseling for Patients
  - Initial and Subsequent Prescription Requirements

REVLIMID REMS™ Resources for Prescribers Include:

- Prescriber Guide to REVLIMID REMS™ Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for REVLIMID

Revlimid® (lenalidomide) capsules

Reference ID: 3319577

Table of contents

About REVLIMID® (lenalidomide)

REVLIMID in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Risks of REVLIMID

REVLIMID has a Boxed Warning for embryo-fetal toxicity, hematologic toxicity, and deep venous thrombosis (DVT) and pulmonary embolism (PE).

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID if they take adequate precautions to avoid pregnancy.

REVLIMID is associated with significant neutropenia and thrombocytopenia in patients with del 5q MDS. Many patients taking REVLIMID may require dose interruption and/or reduction. Evaluate your del 5q MDS patients closely for cytopenias. Patients on REVLIMID should have their complete blood counts monitored weekly for the first 8 weeks of therapy, and at least monthly thereafter.

There is a significant risk of deep venous thrombosis and pulmonary embolism in patients with MM taking REVLIMID plus dexamethasone in combination. Patients and physicians should 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, or arm or leg swelling.

It is not known if preventive anticoagulation or antiplatelet therapy prescribed in conjunction with REVLIMID may lessen the potential for thromboembolic events. The decision to take prophylactic measures should be done carefully after an assessment of an individual patient's underlying risk factors.

The REVLIMID REMS™ program

To avoid embryo-fetal exposure, REVLIMID® (lenalidomide) is only available under a restricted distribution program called "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™." Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID in the REVLIMID REMS™ program.

In order to receive REVLIMID, all patients must be enrolled in REVLIMID REMS™ and agree to comply with the requirements of the REVLIMID REMS™ program. Information about REVLIMID and the REVLIMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

Key points of the REVLIMID REMS™ program

Prescriber

- The prescriber enrolls and becomes certified with Celgene for the REVLIMID REMS™ program
- The prescriber counsels patient on benefits and risks of REVLIMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a REVLIMID® (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends REVLIMID prescription to certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for REVLIMID REMS™
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses REVLIMID to patient along with a Medication Guide

REVLIMID REMS™ patient enrollment

- Obtain, review, and complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**
- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with REVLIMID REMS™ program materials. For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the REVLIMID® (lenalidomide) Patient-Physician Agreement Form in the language of their choice

Help Ensure Timely Processing of Each Prescription

Fill Out Form as Directed

- Write only in the designated areas on the REVLIMID® (lenalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an "X") to indicate understanding
- The form must be completed and signed by both prescriber and patient

Instructions for Female Patients

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

Instructions for Minors

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an "X"), and agree to ensure compliance by signing and dating the form

Instructions for Incompetent Adult Patients

- For an incompetent adult patient, an authorized representative must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form

REVLIMID REMS™ patient enrollment (continued)

- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient's behalf
- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMS™ program and is authorized to consent to treatment with REVLIMID on behalf of the patient

Send in Completed Forms

- Send the completed REVLIMID® (lenalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once REVLIMID® (lenalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

Note: If therapy with REVLIMID is discontinued for 12 consecutive months, the patient must enroll again in the REVLIMID REMS™ program. Follow the above procedures to re-enroll the patient.

Initial prescription requirements

ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with REVLIMID® (lenalidomide)
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with REVLIMID
- Provide counseling not to share REVLIMID capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of REVLIMID, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the REVLIMID REMS™ Patient Resource Pack
- Patients should be instructed to not extensively handle or open REVLIMID capsules
- Instruct patients to return unused REVLIMID capsules for disposal to Celgene or to their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them

FEMALE PATIENTS

Determine if female patient is of reproductive potential

Two categories:

1. Females of Reproductive Potential

- All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category

2. Females Not of Reproductive Potential

- Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

Initial prescription requirements (continued)

1. Females of Reproductive Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for REVLIMID® (lenalidomide) and again within 24 hours prior to writing an initial prescription for REVLIMID even if continuous abstinence is the chosen method of birth control
  - The pregnancy test must be sensitive to at least 50 mIU/mL
  - Pregnancy testing should occur weekly during the first 4 weeks of use
  - Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
  - If a patient misses her period or if there is any abnormality in menstrual bleeding, REVLIMID should be discontinued immediately. Obtain a pregnancy test and counsel the patient
- **If pregnancy does occur during treatment, REVLIMID must be immediately discontinued.** Any suspected embryo-fetal exposure to REVLIMID must be reported immediately to the FDA via the MedWatch number at **1-800-332-1088** and also to the Celgene Customer Care Center at **1-888-423-5436**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with REVLIMID

Initial prescription requirements (continued)

Patient Counseling on Contraception Requirements

Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before REVLIMID® (lenalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control to Use Together

Highly effective birth control methods		Additional effective birth control methods
• Intrauterine device (IUD) • Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) • Tubal ligation (having your tubes tied) • Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	+	• Male latex or synthetic condom • Diaphragm • Cervical cap

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

- **Unacceptable forms of contraception:**
  - Progesterone-only "mini-pills"
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield*
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

Initial prescription requirements (continued)

2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy
- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before REVLIMID® (lenalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking REVLIMID therapy is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of REVLIMID

Del 5q MDS PATIENTS

- Evaluate your del 5q MDS patients closely for cytopenias. Obtain a weekly CBC for the first 8 weeks of treatment, and at least monthly thereafter

Initial mandatory confidential survey

Females

- Instruct the female patient to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements

Males

- Males do not need to take the initial survey

Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
  - Prescriber's identification number
  - Patient's identification number
  - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
  - Average daily dose
  - Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

ADDITIONAL INFORMATION FOR THE PRESCRIBER

- Healthcare provider must send the prescription to a REVLIMID REMS™ certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

Subsequent prescription requirements

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for REVLIMID® (lenalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

FEMALE PATIENTS

- Provide counseling as outlined in the "FEMALE PATIENTS" section on pages 7-10
- Follow pregnancy test requirements as outlined in "Pregnancy test requirements" section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
  - Before prescription is obtained
  - Monthly
    - Adult females of reproductive potential
    - All female children
  - Every 6 months
    - Adult females not of reproductive potential

MALE PATIENTS

- Provide patient counseling as outlined in the "MALE PATIENTS" section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
  - Males do not complete an initial survey

Del 5q MDS PATIENTS

- Evaluate your del 5q MDS patients closely for cytopenias. Obtain a weekly CBC for the first 8 weeks of treatment and at least monthly thereafter

After the last dose of REVLIMID® (lenalidomide)

After patients have stopped taking REVLIMID, they must do the following:

ALL PATIENTS

- Must not share REVLIMID capsules—especially with females of reproductive potential
- Must return any unused REVLIMID capsules for disposal to Celgene or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them
- Must not donate blood for 4 weeks after stopping REVLIMID

FEMALE PATIENTS

- Must not get pregnant for at least 4 weeks after stopping REVLIMID by using the appropriate contraceptives each time engaging in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping REVLIMID
- Must not donate sperm for 4 weeks after stopping REVLIMID

Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

- Materials are available in 16 languages and include:
  - REVLIMID® (lenalidomide) Patient-Physician Agreement Forms
  - Patient Guide to REVLIMID REMS™ Program
  - Mandatory confidential survey forms

Available languages:

Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- REVLIMID® (lenalidomide) Patient-Physician Agreement Forms, Patient Guide to REVLIMID REMS™ Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

Name
Identification Number
Full Address
Fax Number

Patient's:

Name
Full Address
Phone Number
Date of Birth
Identification Number
Diagnosis (most recent version of ICD code)

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of REVLIMID® (lenalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online: **https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com,** or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

Celgene

RevlimidREMS™

Revlimid® (lenalidomide) capsules

RevlimidREMS™

Program for REVLIMID® (lenalidomide) Education and Prescribing Safety

Dear Prescriber:

Enclosed are your REVLIMID REMS™ program education materials.

Celgene Corporation is pleased to provide you with the enclosed materials for use in the REVLIMID REMS™ program (formerly known as the RevAssist® program).

Important Information about the REVLIMID REMS™ program

- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™"
- Lenalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with lenalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of lenalidomide in human semen. Male patients taking REVLIMID should not donate sperm. Males receiving REVLIMID must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with REVLIMID REMS™ can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMS™ program

As a prescriber certified with the REVLIMID REMS™ program, please review and familiarize yourself with the contents of the enclosed REVLIMID REMS™ Kit:

Prescriber Materials

- REVLIMID REMS™ software and Installation Guide
- Prescriber Guide to the REVLIMID REMS™ Program
- REVLIMID Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to REVLIMID REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jerome B. Zeldis, MD, PhD

Chief Medical Officer

Enclosures

Risks of REVLIMID® (lenalidomide)

- REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or embryo-fetal death. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

REVLIMID in combination with dexamethasone is indicated for the treatment of multiple myeloma (MM) patients who have received at least one prior therapy.

REVLIMID is indicated for patients with transfusion-dependent anemia due to Low- or Intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

Celgene

RevlimidREMS™

Revlimid® (lenalidomide) capsules

REMS-REV13260

Revlimid REMS™

Prescriber Enrollment Form

All prescribers must be certified to prescribe REVLIMID® (lenalidomide). To become certified the prescriber must:

1. **Complete the Prescriber Enrollment Form, which is required for REVLIMID REMS™ (formerly known as the RevAssist® program) certification.**
2. **Agree to steps on the following page that must be followed with every patient.**

To submit this form electronically, please go to www.CelgeneRiskManagement.com.

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy.

Please review the steps on the following page that must be followed with every patient.

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Revlimid® (lenalidomide) capsules

REVLIMID REMS™ Prescriber Enrollment Form

When prescribing REVLIMID® (lenalidomide), I agree to:

- Provide patient counseling on the benefits and risks of REVLIMID therapy, including Boxed Warnings
- Submit a completed REVLIMID® (lenalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during REVLIMID treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed REVLIMID immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a REVLIMID REMS™ certified pharmacy to fill the prescription
- Return to Celgene all REVLIMID capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all REVLIMID capsules to Celgene Corporation or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them
- Re-enroll patients in the REVLIMID REMS™ program if REVLIMID is required and previous therapy with REVLIMID has been discontinued for 12 consecutive months

Please fill out the spaces below completely.

Prescriber Name _____

Degree: MD/DO/PA/NP/Fellow/Medical Resident

Specialty _____

Prescriber Identification Number _____

Please indicate which office(s) will receive REVLIMID REMS™ materials and updates:

❑ Primary Office Name _____

Attention _____

Address _____

City _____ State _____ ZIP Code _____

Phone _____ Ext. _____ Fax _____

Email Address _____

❑ Secondary Office Name _____

Attention _____

Address _____

City _____ State _____ ZIP Code _____

Phone _____ Ext. _____ Fax _____

Email Address _____

I understand that if I fail to comply with all requirements of the REVLIMID REMS™ program, my prescriptions for REVLIMID® (lenalidomide) will not be honored at certified pharmacies.

Prescriber Signature _____ Date _____

Return this form to the Celgene Customer Care Center via fax or mail.

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901
Phone: **1-888-423-5436**
Fax: **1-888-432-9325**
www.CelgeneRiskManagement.com

Celgene

RevlimidREMS™

Revlimid® (lenalidomide) capsules

RevlimidREMS™ Education and counseling checklist for pharmacies

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program) education and prescribing safety

Authorization No.: _____ Confirmation No.: _____ Confirmation Date: _____

Pharmacy Name: _____

Pharmacy Address: _____

Counselor Name: _____ Work Phone: _____ Ext.: _____

Patient Name: _____ Date of Birth: _____ Patient I.D. No.: _____

Risk Category: _____

Checklist for female patients of reproductive potential

❑ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

❑ Potential embryo-fetal toxicity

❑ Not taking REVLIMID® (lenalidomide) if pregnant or breastfeeding

❑ Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male

❑ Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking REVLIMID, while taking REVLIMID, during dose interruptions, and for at least 4 weeks after stopping REVLIMID **every time they have sex with a male**, or abstaining from sex with a male

❑ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks

❑ The need to stop taking REVLIMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately

❑ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism

❑ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID

❑ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant

❑ Not donating blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

❑ Not breaking, chewing, or opening REVLIMID capsules

❑ Instructions on REVLIMID dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

❑ Parent or legal guardian must have read the REVLIMID REMS™ education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

❑ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

❑ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism

❑ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID

❑ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant

❑ Not donating blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

❑ Not breaking, chewing, or opening REVLIMID capsules

❑ Instructions on REVLIMID dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

❑ Parent or legal guardian must have read the REVLIMID REMS™ education material and agreed to ensure compliance

❑ Parent or legal guardian must inform the child's doctor when the child begins menses

(continued on next page)

Checklist for male patients

❑ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

❑ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant)

❑ Female partners of males taking REVLIMID® (lenalidomide) must call their healthcare provider right away if they get pregnant

❑ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism

❑ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID

❑ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant

❑ Not donating blood or sperm while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

❑ Not breaking, chewing, or opening REVLIMID capsules

❑ Instructions on REVLIMID dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

MALE CHILDREN (<18 YEARS OF AGE):

❑ Parent or legal guardian must have read the REVLIMID REMS™ education material and agreed to ensure compliance

Rules for dispensing and shipping

DO NOT DISPENSE OR SHIP REVLIMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

❑ Prescription has an authorization number and patient risk category written on it

❑ You have counseled the patient

❑ You have obtained a confirmation number and a confirmation date

❑ You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained

❑ The Medication Guide is included with the prescription

❑ You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing REVLIMID prescription

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: _____ **Date:** _____

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

Celgene

RevlimidREMS™

Revlimid® (lenalidomide) capsules

Pharmacy Guide to

Revlimid REMS™

Risk Evaluation and Mitigation Strategy (REMS)™ Program

Important information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program

- REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™" (formerly known as the RevAssist® program)
- Only prescribers and pharmacies certified with the REVLIMID REMS™ program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the REVLIMID REMS™ program
- Dispensing pharmacists must be educated on the REVLIMID REMS™ program and on dispensing procedures for REVLIMID
- Information about REVLIMID and the REVLIMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

Revlimid®
(lenalidomide) capsules

Reference ID: 3319577

Table of contents

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide)

Dispensing pharmacies must be certified in the REVLIMID REMS™ program with Celgene and must be educated in the following dispensing procedures.

Step 1. Review incoming REVLIMID prescriptions

A. Only accept prescriptions with an authorization number and patient risk category written on them.

- Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
- Faxed prescriptions are permissible depending on state laws

B. Make sure the prescription is signed and dated.

C. Confirm the prescription is written for a 4-week (28-day) supply or less.

D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

Step 2. Counsel patient

A. Make sure a **certified REVLIMID REMS™** counselor counsels the patient.

B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.

C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID, make sure to document these experiences using acceptable documentation as noted on the checklist.

- **Acceptable documentation examples:**
  1. Celgene ADE form and fax confirmation
  2. Pharmacy log

D. Report adverse drug experiences that are suspected to be associated with the use of REVLIMID to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide) (continued)

Step 3. Obtain confirmation number from Celgene Customer Care

A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week.

- Enter the pharmacy NABP number or DEA number
- Enter the authorization number written on the prescription
- Enter the number of capsules and milligram strength being dispensed

B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.

C. If you do not obtain a confirmation number, do not dispense REVLIMID.

Step 4. Dispensing

A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**

B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.

C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.

- **Acceptable documentation examples:**

  1. Signed Education and Counseling checklist (if counseling pharmacist and dispensing pharmacist are the same)
  2. Pharmacy log

D. Document the dispense date and maintain a record on acceptable documentation.

- **Acceptable documentation examples:**

  1. Shipping receipt
  2. Pharmacy dispensing log

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide) (continued)

E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.

F. A signature is required for all shipping and dispense if picked up by patient.

Step 5. Perform drug accountability

A. Pharmacy shall keep an inventory log for REVLIMID, by strength, reflecting its on-hand inventory at all times.

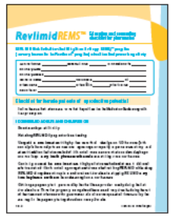
B. Do not transfer REVLIMID to another pharmacy without prior authorization from Celgene.

C. Accept unused REVLIMID (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ education and counseling checklist for pharmacies

Ensure your patients know the risks

Before you are able to fill a prescription for REVLIMID® (lenalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off (☑) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.


RevlimidREMS™

Be prepared to provide the following information for each checklist:

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	Patient Identification Number

Rules for dispensing and shipping

Making sure before you release REVLIMID

DO NOT DISPENSE OR SHIP REVLIMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing REVLIMID prescription

For further information about REVLIMID, please refer to the full Prescribing Information, enclosed.

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of REVLIMID® (lenalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: **https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

Revlimid REMS™

1/13
REMS-REV12114

Revlimid REMS™

Patient Resource Pack

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program)

The Patient Resource Pack contains:

- Patient Guide to REVLIMID REMS™ Program
- Emergency Contraception Brochure
- Medication Guide

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

Celgene

Revlimid® (lenalidomide) capsules

1/13

REMS-REV12104

Reference ID: 3319577