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NDA 21-880 REVLIMID® (lenalidomide)

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

RevAssist® Program

1. GOALS

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

1. To prevent the risk of 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. Medication Guide

A Medication Guide for REVLIMID is dispensed with each prescription for REVLIMID in accordance with 21 CFR 208.24, as described below.

The Medication Guide (MG) along with the package insert (PI) is attached to each bottle of REVLIMID capsules. Five additional Medication Guides per bottle will be included to provide the pharmacist with enough copies to ensure every patient receives a MG with each prescription.

Please see the appended Medication Guide.

2.2. Elements to Assure Safe Use

2.2.1. Healthcare providers who prescribe REVLIMID® are specially certified in the RevAssist® Program.

Celgene will ensure that healthcare providers who prescribe REVLIMID are specially certified in the RevAssist® Program. To become certified, each prescriber must complete the Prescriber Registration 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. Complete and submit to the Celgene Customer Care Center via mail, fax, or online, 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 RevAssist® 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 childbearing 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).
f. Complete a prescriber survey for every patient (new and follow-up), obtain a new authorization number for each prescription written, and include this authorization number on every prescription.
g. Facilitate compliance with the mandatory RevAssist® Program patient survey by instructing patients to complete the mandatory phone surveys 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 RevAssist® Program contract pharmacy to fill the REVLIMID prescription.
j. Return all unused REVLIMID brought in by patients to Celgene Customer Care.
k. Re-register patients in the RevAssist® Program if REVLIMID is required and previous therapy with REVLIMID has been discontinued for 12 consecutive months.

Celgene will:

1. Maintain a secure database of all RevAssist® Program certified prescribers.
2. Monitor to ensure that only RevAssist® Program certified prescribers are prescribing REVLIMID.
3. 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 registration process:
    a. **Adult female of childbearing potential:** all females who are menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal.
    b. **Female child of childbearing potential:** all females under 18 years who are menstruating.
    c. **Adult female NOT of childbearing potential:** females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oopherectomy.

d. **Female child NOT of childbearing potential:** all females under 18 years who are not menstruating.
e. **Adult males 18 years or older**
f. **Male child under 18 years**

4. Monitor certified prescriber compliance with the RevAssist® Program, including patient risk categorization and the appropriate corresponding counseling requirements, contraception requirements, pregnancy testing, and survey completion for all patients treated with REVLIMID.
5. Institute corrective action and prevent the certified prescriber from prescribing REVLIMID if the prescriber is found to be non-compliant with the RevAssist® Program.
6. Train RevAssist® Program certified prescribers in adverse experience reporting procedures, including the requirement to immediately report to Celgene any suspected fetal exposure to REVLIMID if a pregnancy occurs, by providing to the prescriber the "Healthcare Professional Adverse Drug Experience Reporting Procedure".
7. Ensure that once the prescriber submits the completed PPAF, the prescriber will receive a confirmation letter via fax to confirm the patient's enrollment and signify that the prescriber and patient telephone surveys can be taken to receive an authorization number for the REVLIMID prescription (for all males, the PPAF is considered the initial telephone survey). The authorization number is written on the REVLIMID prescription
8. Ensure that, for subsequent prescriptions, the prescriber completes a telephone 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 monthly 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:

1) Prescriber Registration Form
2) Patient-Physician Agreement Form (PPAF)
3) Patient Registration Application Software and User Guides
4) Prescriber Quick Reference Guide
5) Program overview (RevAssist® at A Glance)
6) RevAssist® Prescriber Guide to English and Non-English Materials
7) RevAssist® Instructions for Prescribers
8) RevAssist® Patient Resource Pack
9) Healthcare Professional Adverse Drug Experience Reporting Procedure

2.2.2. REVLIMID® will only be dispensed by pharmacies that are specially certified in the RevAssist® Program.

Celgene will ensure that Revlimid is only dispensed from certified pharmacies. To become a RevAssist® Program certified pharmacy: a contract is negotiated between the pharmacy and Celgene; the pharmacy completes a RevAssist® Program registration form; and the pharmacy must agree to do the following before filling a REVLIMID prescription:

a. Verify that a valid RevAssist® Program authorization number is written on each prescription and is valid for only 7 days for females of childbearing potential and for only 14 days for all other patients.
b. Confirm that the prescription is no more than a 28-day supply and there are 7 days or less remaining on an existing REVLIMID prescription.
c. Call each unique authorization number into the automated system at the Celgene Customer Care Center and obtain a confirmation number, using the following procedure:
    1. Enter the pharmacy identification number (NABP or DEA);
    2. Enter the authorization number written on the prescription;
    3. Enter the number of capsules and milligram (mg) strength being dispensed;
    4. Obtain a confirmation number through the Interactive Voice Response (IVR) system or through a Customer Care Center Representative, and write this number on the prescription.
    5. Dispense or ship the prescribed REVLIMID within 24 hours of obtaining and recording the confirmation number.
d. Dispense no more than a 4-week (28-day) supply, along with the Medication Guide and require a new prescription from the patient prior to dispensing additional REVLIMID.
e. Dispense REVLIMID only after a RevAssist® 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. For each patient receiving treatment, retain a record of each REVLIMID prescription dispensed and the corresponding completed RevAssist® Education and Counseling Checklist.
g. Complete the checklist that applies to the RevAssist® Program patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.
h. Provide counseling to patients and/or guardians of underage patients receiving REVLIMID treatment.

    a. Counsel all patients and guardians of underage patients on the following:

        1. The benefits and risks of REVLIMID therapy.
        2. Not sharing REVLIMID medication
        3. Not donating blood while taking REVLIMID 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 RevAssist® Program education materials and encourage compliance with the requirements.

b. In addition to above, counsel **Females of Childbearing Potential (FCBP)** on the following:

    1. The potential for fetal harm 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 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 fetal harm with exposure to REVLIMID and the importance of using barrier contraception by wearing a latex condom when engaging in sexual intercourse with a female of childbearing potential even if the male receiving REVLIMID has had a successful vasectomy.

d. Counsel the **Parent or legal guardian of Female Child NOT of childbearing 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 RevAssist® Program
2. about the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected fetal exposure to REVLIMID if a pregnancy occurs, by providing to the pharmacist the "Healthcare Professional Adverse Drug Experience Reporting Procedure".

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

1. Guidelines for Ordering, Counseling, and Dispensing REVLIMID
2. Education and Counseling Checklist for Pharmacies
3. Healthcare Professional Adverse Drug Experience Reporting Procedure

2.2.3. Celgene will ensure that REVLIMID® will only be dispensed to patients enrolled in the RevAssist® Program with evidence or other documentation of safe-use conditions.

Celgene will ensure that all patients treated with REVLIMID are enrolled in the RevAssist® Program by a registered prescriber and that each patient and/or guardian of underage patients 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;

   v. they might be asked to participate in the REVLIMID Pregnancy Exposure Registry;

   vi. they may be asked to participate in an additional voluntary survey about the REMS; and

   vii. they may be contacted by Celgene about following the rules of the REMS.

   In addition, each patient and/or guardian of underage patients consents to participate in the program by:

   i. agreeing to return unused REVLIMID to Celgene;

   ii. agreeing to participate in a monthly telephone survey while on REVLIMID (with the exception of Adult Females Not of Childbearing Potential who are required to take a survey once every six months); and

   iii. reviewing the RevAssist® Program educational materials and Medication Guide and asking their prescriber any questions that have not been answered.

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

Females of childbearing potential (FCBP) and guardians of underage FCBP will attest that they/their child:

a. is not currently pregnant, and will try to refrain from becoming pregnant while receiving REVLIMID therapy, during dose interruptions, 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 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 the first 4 weeks of REVLIMID therapy, and then every 4 weeks if the FCBP has regular menstrual cycles, or every 2 weeks if the FCBP 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 FCBP or guardian of an underage FCBP can call Celgene Drug Safety via 1-888-423-5436 or 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 woman who can become pregnant;
b. wear a latex condom every time the male patient has sexual contact with a woman who is or who can become pregnant; continue condom use with sexual contact while the male patient is receiving REVLIMID treatment 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 woman 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 Celgene Drug Safety via 1-888-423-5436 or 1-888-668-2528 for information on emergency contraception.
d. will not donate sperm while taking and for 4 weeks after stopping REVLIMID

Celgene will ensure that a completed PPAF is submitted via fax, email or online for each patient who receives REVLIMID.

The following appended materials are part of the REMS:

1) Patient Resource Pack including Important Information for Men and Women Taking REVLIMID
2) Patient Registration and Patient-Physician Agreement Form Adult Male
3) Patient Registration and Patient-Physician Agreement Form for Male Child
4) Patient Registration and Patient-Physician Agreement Form for Adult Female NOT of Childbearing Potential
5) Patient Registration and Patient-Physician Agreement Form for Adult Female of Childbearing Potential
6) Patient Registration and Patient-Physician Agreement Form for a Female Child NOT of Childbearing Potential
7) Patient Registration and Patient-Physician Agreement Form for a Female Child of Childbearing Potential

2.2.4. 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.

The registry will collect the following information:

Upon receiving a report of pregnancy from the RevAssist® 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 childbearing potential and male patients' female partners who are exposed to REVLIMID and to understand why the RevAssist® program was unsuccessful.

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

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

2.3. Implementation System

The implementation system will include the following:

1) Celgene will maintain a secure database of all certified entities, including enrolled patients and pharmacies to monitor and evaluate implementation of the elements provided for in Sections 2.2.3 and 2.2.4.
2) Celgene will monitor RevAssist® Program certified pharmacy 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 RevAssist® Program, Celgene will institute corrective action and may de-activate pharmacies for which re-training has proven ineffective, removing them from the RevAssist® Program.
    b. Celgene will perform regular on-site audits of contract pharmacies participating in the RevAssist® 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 RevAssist® Program compliance audits will be performed by internal auditors of Celgene and/or outside auditors contracted and trained by Celgene—the auditors will be independent of every other organization responsible for the sales of REVLIMID or the effective operations of the RevAssist® Program.
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 RevAssist® Program and any distribution and dispensing of REVLIMID. With the "real-time" intervention of the Risk Management Intervention Specialist, most issues will be addressed within one day.
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 RevAssist® 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.

2.4. Timetable for Submission of Assessment Reports

REMS assessments (RevAssist® Program update reports) will be submitted at six months and then annually following REMS approval. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will 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.

MEDICATION GUIDE
REVLIMID® (rev-li-mid)
(lenalidomide)
Capsules

Read the Medication Guide that comes with REVLIMID before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about REVLIMID?

- Before you begin taking REVLIMID, you must read and agree to all of the instructions in the RevAssist® program.

- REVLIMID may cause serious side effects including:

  Possible birth defects (deformed babies) or death of an unborn baby. Females who are pregnant or who plan to become pregnant must not take REVLIMID.

  REVLIMID is similar to the medicine thalidomide (THALOMID®). We know thalidomide can cause severe life-threatening birth defects. REVLIMID has not been tested in pregnant women. REVLIMID has harmed unborn animals in animal testing.

  Females must not get pregnant:
  - for 4 weeks before starting REVLIMID
  - while taking REVLIMID
  - during any breaks (interruptions) in your treatment with REVLIMID
  - for 4 weeks after stopping REVLIMID

  If you become pregnant while taking REVLIMID, stop taking it right away and call your healthcare provider. If your healthcare provider is not available, you can call 1-888-668-2528 for medical information. Healthcare providers and patients should report all cases of pregnancy to:
  - FDA MedWatch at 1-800-FDA-1088, and
  - Celgene Corporation at 1-888-423-5436

  REVLIMID can pass into human semen:

  - Males, including those who have had a vasectomy, must use a latex condom during any sexual contact with a pregnant female or a female that can become pregnant while taking REVLIMID, during any breaks (interruptions) in your treatment with REVLIMID, and for 4 weeks after stopping REVLIMID. (If you or your partner are allergic to latex, please consult with your healthcare provider)

- Do not have unprotected sexual contact with a female who is or could become pregnant. Tell your healthcare provider if you do have unprotected sexual contact with a female who is or could become pregnant.

- Do not donate sperm while taking REVLIMID, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID. If a female becomes pregnant with your sperm, the baby may be exposed to REVLIMID and may be born with birth defects.

Men, if your female partner becomes pregnant, you should call your healthcare provider right away.

Low white blood cells (neutropenia) and low platelets (thrombocytopenia).
REVLIMID causes low white blood cells and low platelets in most patients. You may need a blood transfusion or certain medicines if your blood counts drop too low. If you are being treated for del 5q myelodysplastic syndromes (MDS) your blood counts should be checked weekly during the first 8 weeks of treatment with REVLIMID, and at least monthly thereafter. If you are being treated for multiple myeloma, your blood counts should be checked every 2 weeks for the first 12 weeks and then at least monthly thereafter.

A higher chance for blood clots in your veins and lungs. Call your healthcare provider or get medical help right away if you get any of these signs or symptoms:

- shortness of breath
- chest pain
- arm or leg swelling

What is REVLIMID?

REVLIMID is a prescription medicine taken by mouth to treat certain patients who have myelodysplastic syndromes (MDS). People with MDS have bone marrow that does not produce enough mature blood cells. This causes a lack of healthy blood cells that can function properly in the body. There are different types of MDS. REVLIMID is for the type of MDS with a chromosome problem where part of chromosome 5 is missing. This type of MDS is known as deletion 5q MDS. People with this type of MDS may have low red blood cell counts that require treatment with blood transfusions.

REVLIMID is also used with dexamethasone to treat people with multiple myeloma who have already had another treatment. Multiple myeloma is a cancer of plasma cells. Plasma cells are found in the bone marrow. Normal plasma cells produce proteins called antibodies. Some antibodies can attack and kill disease causing germs. People with multiple myeloma may have low blood cell counts and immune problems giving them a higher chance for getting infections such as pneumonia. They may also have bone pain and breaks (fractures).

Who should not take REVLIMID?

- Do not take REVLIMID if you are pregnant, plan to become pregnant, or become pregnant during REVLIMID treatment. See "What is the most important information I should know about REVLIMID?"

- Do not take REVLIMID if you are allergic to anything in it. See the end of this Medication Guide for a complete list of ingredients in REVLIMID.

What should I tell my healthcare provider before taking REVLIMID?

Tell your healthcare provider about all of your medical conditions, including if you:

- are lactose intolerant. REVLIMID contains lactose.

- **are pregnant or breastfeeding.** REVLIMID must not be used by women who are pregnant or breastfeeding. See "What is the most important information I should know about REVLIMID?" It is not known if REVLIMID passes into your breast milk and harms your baby.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements. REVLIMID and other medicines may affect each other causing serious side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

How should I take REVLIMID?

Take REVLIMID exactly as prescribed and follow all the instructions of the RevAssist program.

Before prescribing REVLIMID, your healthcare provider will:

- explain the RevAssist program to you
- have you sign the Patient-Physician Agreement Form

- Swallow REVLIMID capsules whole with water once a day. **Do not break, chew, or open your capsules.**

- Do not open the REVLIMID capsules or handle them any more than needed. If you touch a broken REVLIMID capsule or the medicine in the capsule, wash the area of your body with soap and water.

- If you miss a dose of REVLIMID, and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, just skip your missed dose. Do **not** take 2 doses at the same time.

- If you take too much REVLIMID or overdose, call your healthcare provider or poison control center right away.

Females who can become pregnant:

- will have pregnancy tests weekly for 4 weeks, then every 4 weeks if your menstrual cycle is regular, or every 2 weeks if your menstrual cycle is irregular.

  If you miss your period or have unusual bleeding, you will need to have a pregnancy test and receive counseling.

- must agree to use 2 different forms of effective birth control at the same time, for 4 weeks before, while taking, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID.

Males who take REVLIMID, even those who have had a vasectomy, must agree to use a latex condom during sexual contact with a pregnant female or a female who can become pregnant. (If you or your partner is allergic to latex, please consult with your healthcare provider.)

What should I avoid while taking REVLIMID?

- **Females: Do not get pregnant and do not breastfeed while taking REVLIMID.**
  Males: Do not donate sperm, See "What is the most important information I should I know about REVLIMID?", "Who should not take REVLIMID?", and "What should I avoid while taking REVLIMID?".

- **Do not share REVLIMID with other people.** It may cause birth defects and other serious problems.

- **Do not donate blood** while you take REVLIMID, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID. If someone who is pregnant gets your donated blood, her baby may be exposed to REVLIMID and may be born with birth defects.

What are the possible side effects of REVLIMID?

- **REVLIMID may cause serious side effects.**

- See "What is the most important information I should know about REVLIMID?"

- **Serious skin reactions**. Serious skin reactions can happen with REVLIMID and may cause death. Call your healthcare provider right away if you have any skin reaction while taking REVLIMID.

- **Tumor lysis syndrome.** Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the breakdown products of dying cancer cells and may include the following: changes to blood chemistry, high potassium, phosphorus, uric acid, and low calcium that may lead to changes in kidney function, heart beat, seizures, and sometimes death.

- **Risk of new cancers (malignancies).** People with multiple myeloma who receive melphalan (a type of chemotherapy) or a blood stem cell transplant with the addition of REVLIMID have a higher risk of developing new cancers, including certain blood cancers (acute myelogenous leukemia or AML) and a type of lymphoma called Hodgkin lymphoma. Talk with your healthcare provider about your risk of developing new cancers if you take REVLIMID. Your healthcare provider will check you for new cancers during your treatment with REVLIMID.

Common side effects of REVLIMID are:

- diarrhea
- itching
- rash
- tiredness

These are not all the possible side effects of REVLIMID. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store REVLIMID?

- Store REVLIMID at room temperature between, 59°F to 86°F (15°C to 30°C).

Keep REVLIMID and all medicines out of the reach of children.

General information about REVLIMID

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. **Do not** take REVLIMID for conditions for which it was not prescribed. **Do not** give REVLIMID to other people, even if they have the same symptoms you have. It may harm them and may cause birth defects.

This Medication Guide provides a summary of the most important information about REVLIMID. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about REVLIMID that is written for healthcare professionals. You can also call 1-888-423-5436 or visit www.REVLIMID.com.

What are the ingredients in REVLIMID?

Active ingredient: lenalidomide

Inactive ingredients: lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate.

The 5 mg and 25 mg capsule shells contain gelatin, titanium dioxide and black ink. The 2.5 and 10 mg capsule shell contains gelatin, FD&C blue #2, yellow iron oxide,

titanium dioxide and black ink. The 15 mg capsule shell contains gelatin, FD&C blue #2, titanium dioxide and black ink.

This Medication Guide has been approved by the US Food and Drug Administration.

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Manufactured for Celgene Corporation

Summit, NJ 07901

REVLIMID®, RevAssist®, and THALOMID® are registered trademarks of Celgene Corporation.

U.S. Pat. Nos. 5,635,517; 6,045,501; 6,281,230; 6,315,720; 6,555,554; 6,561,976; 6,561,977; 6,755,784; 6,908,432; 7,119,106; 7,189,740; 7,465,800; 7,855,217; 7,968,569

RevAssist® Prescriber Registration

IMPORTANT INFORMATION ABOUT RevAssist®

- To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called "RevAssist®"
- Only prescribers registered with RevAssist® can prescribe REVLIMID® (lenalidomide)
- Only RevAssist® contract pharmacies can dispense REVLIMID® (lenalidomide)
- In order to receive REVLIMID® (lenalidomide), patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program
- Information about REVLIMID® (lenalidomide) and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com

All prescribers MUST be registered to prescribe REVLIMID®. Please review the steps below that MUST be followed with every patient and return this card to Celgene Corporation.

When prescribing REVLIMID®, I agree to:

- Provide patient counseling on the benefits and risks of REVLIMID® therapy, including Boxed WARNINGS
- Provide contraception and emergency contraception counseling in addition to scheduled pregnancy testing for females of childbearing potential
- Submit a completed REVLIMID® Patient-Physician Agreement Form for each new patient to the Celgene Customer Care Center via fax to 1-888-432-9325 or via mail
- Facilitate patient compliance with a mandatory telephone survey
- Complete a brief prescriber telephone survey for all patients and obtain a new authorization number for each prescription written
- Provide authorization number on every prescription
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact RevAssist® contract pharmacy to fill the prescription
- Return to Celgene all REVLIMID® that is returned by patients. Shipping fees will be paid by Celgene Corporation. Call the Celgene Customer Care Center at 1-888-423-5436 to arrange for returns

Please fill out the spaces below completely.

Prescriber Name _____
(Please print name as it appears on your prescription pad)

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

Specialty _____

DEA No. _____ Social Security No. (if no DEA) _____

ME No. _____

Please indicate which office(s) will receive RevAssist® materials and updates:

☐ Primary Office Name _____
Attention (Office RevAssist® Contact) _____
Address _____
City _____ State _____
ZIP _____
Phone _____ Ext. _____ Fax _____
E-mail Address _____

☐ Secondary Office Name _____
Attention (Office RevAssist® Contact) _____
Address _____
City _____ State _____
ZIP _____
Phone _____ Ext. _____ Fax _____
E-mail Address _____

I understand that if I fail to comply with all requirements of the RevAssist® program, my prescriptions for REVLIMID® will not be honored at contract pharmacies.

Prescriber Signature _____ Date _____

Return this card to the Celgene Customer Care Center via fax (1-888-432-9325) or via mail.

Celgene Customer Care Center
1-888-423-5436
Fax 1-888-432-9325
www.REVLIMID.com
86 Morris Avenue, Summit, NJ 07901

Revlimid® (lenalidomide) capsules

03/07 REV05076R1

Fold, peel strip, and seal.

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 101 SUMMIT NJ

POSTAGE WILL BE PAID BY ADDRESSEE

CELGENE CORPORATION
CELGENE CUSTOMER CARE CENTER
86 MORRIS AVENUE
SUMMIT NJ 07901-9920

Includes REVLIMID® Patient-Physician Agreement Form
and REVLIMID® Patient Prescription Form software

RevAssist®

RevAssist® program for REVLIMID® (lenalidomide) education and prescribing safety kit

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

Special Prescribing Requirements

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID® (lenalidomide), REVLIMID® (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED "REVASSIST®". UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID® (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE REVASSIST® PROGRAM.

2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID® (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY PRESCRIBED IN CONJUNCTION WITH REVLIMID® (lenalidomide) MAY LESSEN THE POTENTIAL FOR VENOUS THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT'S UNDERLYING RISK FACTORS.

You can get the information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll free number 1-888-423-5436.

Revlimid®
(lenalidomide) capsules

RevAssist® program for REVLIMID® (lenalidomide) education and prescribing safety kit

Prescriber materials

These materials are provided to assist you in the use of the RevAssist® program.

Included are:

- Software CD-ROM with User Guide for REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form
- RevAssist® At-A-Glance
- Prescriber Guide to English and non-English Materials
- Instructions for Prescribers
- Patient Chart Sticker (located on Patient Resource Pack)
- Full Prescribing Information

Please see complete **Instructions for Prescribers.**

RevAssist®

Patient materials

Every patient must receive a Patient Resource Pack.

Each envelope contains:

- RevAssist® Guide to Patient Surveys
- Important Information for Men and Women Taking REVLIMID® (lenalidomide) Brochure
- Emergency Contraception Brochure
- The FDA-approved MEDICATION GUIDE
  - Each patient must receive the MEDICATION GUIDE with each prescription dispensed

To order additional Patient Resource Packs, please call the Celgene Customer Care Center at 1-888-423-5436 or see your Celgene Hematology Oncology Consultant.

RevAssist®

Prescriber quick reference guide

1. **Healthcare provider provides comprehensive counseling**
2. **Healthcare provider/patient completes REVLIMID® Patient-Physician Agreement Form**
3. **Healthcare provider obtains pregnancy test for females of childbearing potential**
4. **Patient completes telephone survey**
5. **Healthcare provider completes telephone survey and receives authorization number**
6. **Healthcare provider prescribes REVLIMID®**
7. **Healthcare provider sends prescription to a RevAssist® contract pharmacy**

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

For more information about REVLIMID® and RevAssist®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com

This flow sheet should be used only as a quick reference and only after reviewing all RevAssist® Program Procedures.

Celgene

03/07 REV05068R1

Revlimid® (lenalidomide) capsules

Reference ID: 3128570

RevAssist®

For more information about REVLIMID® and RevAssist®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com

Revlimid®
(lenalidomide)capsules

03/07

REV05069R1

RevAssist® Software and User Guide for REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form

RevAssist®

Software and User Guide for REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form

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Revlimid®
(lenalidomide)capsules

Reference ID: 3128570

FPO CD Slit
(to be created by vendor)

Overview

IMPORTANT INFORMATION ABOUT RevAssist®

- To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called "RevAssist®"
- Only prescribers registered with RevAssist® can prescribe REVLIMID® (lenalidomide)
- Only RevAssist® contract pharmacies can dispense REVLIMID® (lenalidomide)
- In order to receive REVLIMID® (lenalidomide), patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program
- Information about REVLIMID® (lenalidomide) and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com

Only the initial registration of patients is conducted via the REVLIMID® Patient-Physician Agreement Forms software.

Under this method of registering patients, the prescriber is provided with a CD-ROM containing the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software. The software is installed on a computer. The installation process is described in detail on page 4.

Based on information the prescriber enters for each patient, the software will determine the risk category in which the patient belongs.

After the patient-specific form is generated within the software, it is printed, initialed by the patient, signed and dated by the patient and the prescriber, then faxed to the Celgene Customer Care Center at 1-888-432-9325.

By registering a patient via the REVLIMID® Patient-Physician Agreement Forms software, the likelihood of human errors is reduced as well as the number of phone calls by the Celgene Customer Care Center to prescribers to gather additional information or to clarify information previously provided.

The CD-ROM contains 6 risk categories:

- Adult Males
- Male Children
- Adult Females of Childbearing Potential
- Adult Females Not of Childbearing Potential
- Female Children of Childbearing Potential
- Female Children Not of Childbearing Potential

Installation on your PC computer

To install the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software (Windows® version):

1. Insert CD-ROM into the computer's CD-ROM drive.
2. Click **Start**.
3. Click **Run**. The Run dialogue box appears.
4. In the Open box, type D:\setup.exe (replace "D" with the letter of your CD-ROM drive, if necessary). Then click **OK**.
5. Click **Next** at the installation welcome screen.
6. Choose a location in which to install the software. To accept the default location, click **Next**.
7. Click **Next** to install the software.
8. Wait for the computer to finish unpacking the files.
9. When the installation is complete, click **Finish**. Remove the CD-ROM.

Now that it is installed on your computer's hard drive, you do not need the CD-ROM to access the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software.

If your computer does not have a CD-ROM drive, please contact your Celgene Hematology Oncology Consultant or call the Celgene Customer Care Center at 1-888-423-5436.

Installation on your Macintosh® computer

To install the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software on Mac OS® X or higher:

1. Insert the CD-ROM into the computer's CD-ROM drive. The RevAssist® CD-ROM icon appears on the desktop.
2. Double-click on the **RevAssist** CD icon.
3. Double-click the **Install RevAssist** icon that appears. The Installation Wizard runs.
4. Install RevAssist®
   a. If you are installing RevAssist® for the first time, select **I am installing RevAssist for the first time** and click **Finish**. This will install the application into the Applications system folder.
   b. If you are currently using a previous version of RevAssist®, select **I already have RevAssist installed** and fill out the 2 boxes corresponding to the previous installation location and location of saved .reg files and click **Finish**.
5. If you upgraded an existing installation, you can run RevAssist® by clicking the same icon as before. If you are installing the software for the first time, click the **Finder** icon and navigate to the **RevAssist** folder **(Applications/Celgene/RevAssist)**. The application is named RevAssist.
6. To remove the CD-ROM, press **Eject** or drag the CD icon to the trash.

Mac OS 8 and OS 9 (Mac® Classic) users should complete these steps:

1. Insert the CD-ROM into the computer's CD-ROM drive. The CD-ROM icon will appear on the desktop.
2. Double-click **RevAssist** CD icon. A window showing the CD contents will appear.
3. Double-click on the **classic** folder to open.
4. Select and copy the contents of this folder to the Mac Classic desktop. The application installed in the folder is named RevAssist.

Now that it is installed on your computer's hard drive, you do not need the CD-ROM to access the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software.

If your computer does not have a CD-ROM drive, please contact your Celgene Hematology Oncology Consultant or call the Celgene Customer Care Center at 1-888-423-5436.

Generating the REVLIMID® Patient–Physician Agreement Form

This section explains the process of generating the most appropriate of the 6 REVLIMID® Patient-Physician Agreement Forms that corresponds to the specific patient's demographic.

In this process, patient and prescriber information is entered into the Patient and Prescriber sections in the REVLIMID® Patient-Physician Agreement Form screen. Data from the Patient and Prescriber sections are then copied into the applicable REVLIMID® Patient-Physician Agreement Form. This form is printed, initialed by the patient, signed and dated by the patient and the prescriber, then faxed to the Celgene Customer Care Center (1-888-432-9325), where the patient registration process is completed by Customer Care Center Representatives.

To generate the REVLIMID® Patient-Physician Agreement Form:

1. **Windows® users:** Click **Start**. Move the cursor until **Programs** is highlighted, choose the **Celgene** folder, choose the **RevAssist Program** folder, choose **RevAssist Program**, and click once.

   Macintosh users: Click the **Finder** icon and navigate to the **RevAssist** folder **(Applications/Celgene/RevAssist)**. Double-click on the **RevAssist** icon.

2. The RevAssist® logo screen will be displayed (Figure 1). Click on the **REGISTER PATIENT** button.

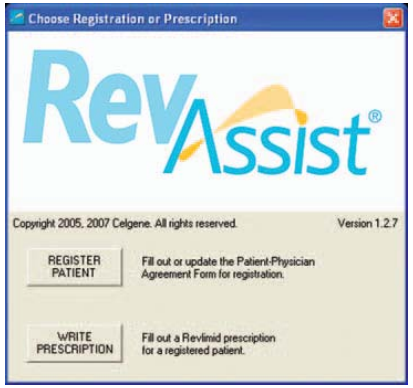

Figure 1
RevAssist® logo screen.

The REVLIMID® Patient-Physician Agreement Form screen (Figure 2) appears.

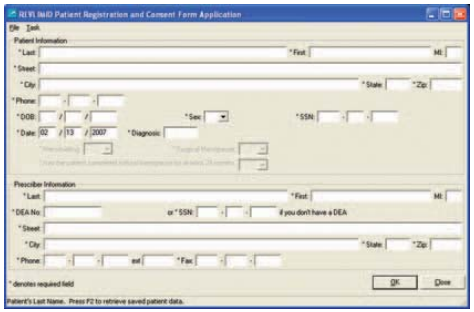

Figure 2
REVLIMID® Patient-Physician Agreement Form screen.

3. Enter information into each of the fields in the Patient Information section located in the upper portion of the REVLIMID® Patient-Physician Agreement Form screen. Note that instructions for each field are displayed at the bottom of the screen, and that:
   - When typing in the year in the **DOB** field, all 4 digits are required
   - The **Date** field automatically fills in the current date. Alternatively, the date may be manually entered
   - The diagnosis can be filled in with the appropriate code by pressing **F2** when the cursor is placed in the **Diagnosis** field. Pressing **F2** displays the Diagnosis Code Search screen. The appropriate diagnosis can then be highlighted and transferred to the **Diagnosis** field on the REVLIMID® Patient-Physician Agreement Form screen by clicking **Accept**

If the patient is female, select the appropriate values for the menstruation, surgical menopause, and natural menopause fields.

Complete the **Prescriber Information** fields in the lower portion of the screen by filling out the **Last Name**, **First Name**, and **Middle Initial**.

Enter your 9-digit **DEA number** or your **Social Security number**.

The personal information for each prescriber needs to be entered only once. To generate subsequent forms for a prescriber, put your cursor in the prescriber **Last Name** field and press **F2**. A list of previously entered prescribers will appear (Figure 3). After highlighting a name, click **OK** to import that data into the REVLIMID® Patient-Physician Agreement Form.

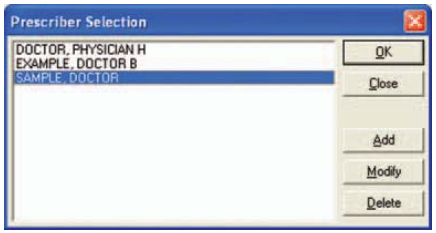

Figure 3
Prescriber selection screen.

Prescribers may be added to this list by clicking **Add**. Prescriber's records may be modified (eg, name change) by clicking **Modify**, and deleted by clicking **Delete**.

Complete the **Prescriber Address** fields in the lower portion of the screen. The address information may be entered by filling out the **Street**, **City**, **State**, and **Zip** fields.

Enter the values for the **Phone Number** and **Fax Number** fields.

The address information for each prescriber needs to be entered only once. To generate subsequent forms for a prescriber, put your cursor in the prescriber **Street** field and press **F2**. A list of previously entered prescribers' addresses will appear (Figure 4). After highlighting an address, click **OK** to import that data into the REVLIMID® Patient-Physician Agreement Form. Prescriber's addresses may be added to this list by clicking **Add**. Prescriber's records may be modified (eg, address change) by clicking **Modify**, and deleted by clicking **Delete**.

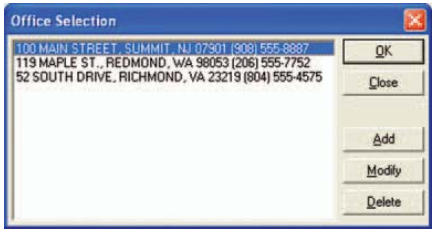

Figure 4
Office selection screen.

Note: After registering your first patient, use the same address in the **Prescriber Information** section if you are registering additional patients out of the same office.

4. The REVLIMID® Patient-Physician Agreement Form will be automatically saved when submitted. Files may be saved manually by selecting **Save** from the File menu. (To retrieve the information at another time, press **F2** from the patient's **Last Name** field or select **Open** from the File menu, select the previously saved file, and either double-click the entry or click **OK**.)

   The information for each patient needs to be entered only once. To access a patient's information from a completed form, open a new REVLIMID® Patient-Physician Agreement Form, place your cursor in the **Last Name** field, and press **F2** or select **Open** from the File menu. A list of previously entered patients will appear. Select the desired patient file, and either double-click the entry or click **OK**. Both the patient information and the information for the patient's prescriber will be imported into the REVLIMID® Patient-Physician Agreement Form.

5. When the REVLIMID® Patient-Physician Agreement Form screen is complete, click **OK**. (A completed screen is shown in Figure 5.)

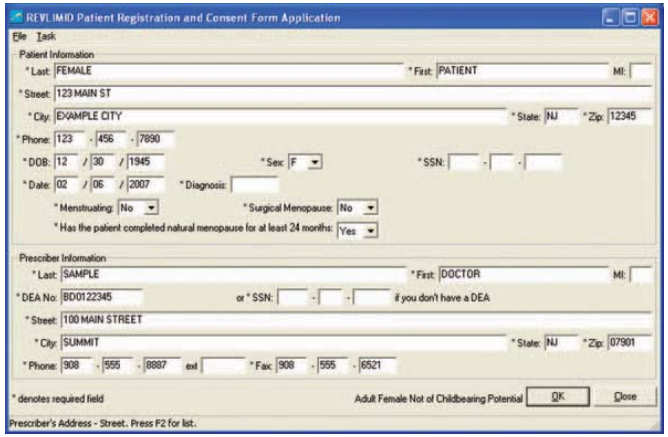

Figure 5
REVLIMID® Patient-Physician Agreement Form screen (completed example).

6. The REVLIMID® Patient-Physician Agreement Form displays. The version of the form is dependent upon the patient's sex and childbearing status.
7. Print the REVLIMID® Patient-Physician Agreement Form. Select **Print** from the File menu or click **Print**. Note that the patient and the prescriber information previously entered into the REVLIMID® Patient-Physician Agreement Form screen has been copied into the form. Now inspect the form for accuracy and completeness.

   At this point, the process of generating the REVLIMID® Patient-Physician Agreement Form is complete.

Next steps

1. Present the REVLIMID® Patient-Physician Agreement Form to the patient. In the course of the prescriber's counseling interview with the patient, the patient signifies his/her consent to the REVLIMID® (lenalidomide) treatment by writing his/her initials in each block of the form.

   A sample of REVLIMID® Patient-Physician Agreement Form is shown in Figure 6.
2. Ensure that the **Patient signs and dates** the form in front of the prescriber.
3. Ensure that the **Prescriber signs and dates** the form.
4. Refrain from writing extraneous handwritten material on the REVLIMID® Patient-Physician Agreement Form other than the patient's initials and the patient's and prescriber's signatures.
5. Fax all pages of the REVLIMID® Patient-Physician Agreement Form to the Celgene Customer Care Center at 1-888-432-9325, as indicated on the bottom of the last page of the REVLIMID® Patient-Physician Agreement Form.

   Once the patient is registered, Celgene will fax a confirmation letter to the prescriber so that both patient and prescriber can take their surveys as required.

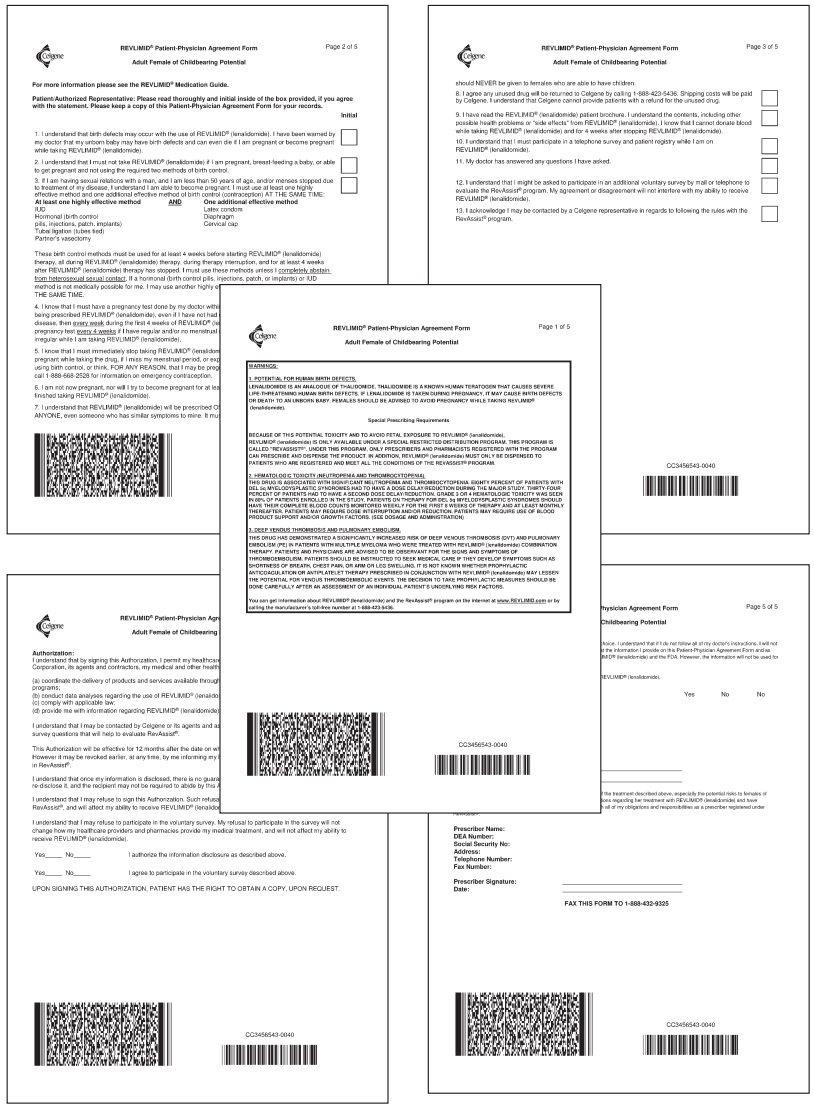

Figure 6
A sample REVLIMID® Patient-Physician Agreement Form. This version of the form is used for an adult female of childbearing potential. Other versions of the form exist for patients of other categories and conditions.

Generating the REVLIMID® Patient Prescription Form

This section explains the process of generating a REVLIMID® Patient Prescription Form for use at a pharmacy that distributes REVLIMID®.

In this process, a registered patient's information is loaded into the REVLIMID® Patient Prescription Form screens and further information is entered about the patient, the prescriber, and the prescription. Data from these sections are then copied into the REVLIMID® Patient Prescription Form. This form is printed, signed, and dated by the prescriber, then faxed to the pharmacist, where the prescription is filled and confirmed with Celgene.

To generate the REVLIMID® Patient Prescription Form:

1. After you have finished with the print preview for the REVLIMID® Patient-Physician Agreement Form, you will automatically be prompted to write a REVLIMID® prescription for the patient. Alternately, you can open the RevAssist® Program again and click **WRITE PRESCRIPTION**. You will be prompted to choose a patient from the list.
2. The software then displays the first screen of the REVLIMID® Patient Prescription Form. Most of the information will be filled in automatically from the record of the registered patient. Enter missing information into the required fields or by using the pull-down menus. Note that instructions for each field are displayed at the bottom of the screen, and that:
   - **Other Phone Number** is optional
   - **Date Rx Needed** and **Language Preference** are required
   - **Patient Allergies** and **Other Current Medications** are required
3. After all information is entered on the first page, click **Next**.
4. The second screen of the REVLIMID® Patient Prescription Form is displayed. Enter required information about the prescriber, including **Physician State License Number**, **Office Contact Name**, and **Office Contact Phone Number**. This screen also contains space for information about **Primary** and **Secondary Insurance**.
5. After all information is entered on the second page, click **Next**.
6. The REVLIMID® Patient Prescription screen is displayed. Check the box that corresponds to the **Dose** in milligram (mg) strength and enter the **Quantity** of capsules. Fill in the medication **Directions** in the space provided. Be sure to select the correct choice of either **Dispense as Written** or **Substitution Permitted**, which will be indicated on the completed form for the pharmacist. Finally, enter the **Authorization Number** obtained from Celgene Customer Care Center.
7. When you are finished with these three screens, press **Print**.
8. The REVLIMID® Patient Prescription Form print preview window appears. The REVLIMID® Patient Prescription Form is now filled out with data collected on the previous screens.
9. Print the REVLIMID® Patient Prescription Form. Select **Print** from the File menu or click **Print**. Check the printed form for accuracy and completeness.

   At this point, the procedure for generating the REVLIMID® Patient Prescription Form is complete.

Next steps

1. Ensure that the **Prescriber signs and dates** the REVLIMID® Patient Prescription Form where indicated in the Prescription section.
2. Refrain from writing extraneous handwritten material on the REVLIMID® Patient Prescription Form other than the prescriber's signature.
3. Fax the REVLIMID® Patient Prescription Form to the pharmacist, as indicated in "How to Fill a REVLIMID® (lenalidomide) Prescription" located on the second page.

   Follow the procedures on the second page of the REVLIMID® Patient Prescription Form to complete the business process.

RevAssist® At-A-Glance

IMPORTANT INFORMATION ABOUT RevAssist®

- To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called "RevAssist®"
- Only prescribers registered with RevAssist® can prescribe REVLIMID® (lenalidomide)
- Only RevAssist® contract pharmacies can dispense REVLIMID® (lenalidomide)
- In order to receive REVLIMID® (lenalidomide), patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program
- Information about REVLIMID® (lenalidomide) and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com

Initial prescription process (for all patients unless otherwise noted)

1. For females of childbearing potential, obtain two 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 within 10–14 days and one test within 24 hours prior to writing an initial prescription of REVLIMID®
2. Obtain a baseline Complete Blood Count
3. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception
4. Complete, print, and sign REVLIMID® Patient-Physician Agreement Form
   - **Males (adults and children)**
   - **Females of childbearing potential include females who have not undergone a natural menopause** for at least 24 consecutive months
   - **Females not of childbearing potential include females who have been postmenopausal naturally** for at least 24 consecutive months, or had a hysterectomy, or a bilateral oophorectomy
5. Fax completed and signed REVLIMID® Patient-Physician Agreement Form to 1-888-432-9325
6. Instruct patient to complete phone survey by calling 1-888-423-5436 prior to prescriber obtaining an authorization number
   - **All males:** REVLIMID® Patient-Physician Agreement Form is considered the initial phone survey
   - **All females:** Complete the appropriate phone survey
7. Complete a prescriber phone survey for all patients by calling 1-888-423-5436 and obtain a new authorization number for each prescription
   - You will need to enter the following information:
     - Prescriber's DEA number or Social Security number
     - Patient's Social Security number
     - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days
     - Daily dose
     - Total number of days supplied (cannot exceed 28 days)

Revlimid® (lenalidomide) capsules

8. Provide the authorization number on the prescription; authorization number and prescription are valid for 7 days for females of childbearing potential and 14 days for all other patients
9. Healthcare provider contacts a RevAssist® contract pharmacy to fill the prescription
10. RevAssist® contract pharmacy contacts patient for counseling and dispenses REVLIMID® (lenalidomide) with the FDA-approved MEDICATION GUIDE and educational material

Subsequent REVLIMID® prescriptions (for all patients unless otherwise noted)

1. For females of childbearing 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. Obtain Complete Blood Counts as necessary
3. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception
4. Instruct patient to complete surveys **as scheduled**, prior to prescriber obtaining an authorization number and filling prescription
   - Monthly:
     - **Males (adults and children)**
     - **Females of childbearing potential (adults and children), female children not of childbearing potential**
   - Every 6 months:
     - **Adult females not of childbearing potential (who have been postmenopausal naturally for at least 24 consecutive months, or had a hysterectomy, or a bilateral oophorectomy)**
5. Complete a prescriber phone survey for all patients by calling 1-888-423-5436 and obtain a new authorization number for each prescription
   - You will need to enter the following information:
     - Prescriber's DEA number or Social Security number
     - Patient's Social Security number
     - Date and result of patient's last pregnancy test (if applicable); valid only for 7 days
     - Daily dose
     - Total number of days supplied (cannot exceed 28 days)
6. Provide the authorization number on the new prescription; authorization number and prescription are valid for 7 days for females of childbearing potential and 14 days for all other patients
7. Healthcare provider contacts RevAssist® contract pharmacy to fill the prescription
8. RevAssist® contract pharmacy contacts patients for counseling and dispenses REVLIMID® with the FDA-approved MEDICATION GUIDE

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

For more information about REVLIMID® and RevAssist®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com

Revlimid®
(lenalidomide) capsules

RevAssist® Prescriber Guide to English and non-English Materials

IMPORTANT INFORMATION ABOUT RevAssist®

- To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called "RevAssist®"
- Only prescribers registered with RevAssist® can prescribe REVLIMID® (lenalidomide)
- Only RevAssist® contract pharmacies can dispense REVLIMID® (lenalidomide)
- In order to receive REVLIMID® (lenalidomide), patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program
- Information about REVLIMID® (lenalidomide) and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com

Call Celgene Customer Care Center 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 RevAssist® program materials. For additional assistance, please contact the Celgene Customer Care Center at 1-888-423-5436 or your Celgene Hematology Oncology Consultant
- Materials are available in 16 languages and include:
  - REVLIMID® Patient-Physician Agreement Forms
  - Patient brochure [Important Information for Men and Women Taking REVLIMID® (lenalidomide)]
  - Survey forms

Available languages:

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

Revlimid® (lenalidomide) capsules

- REVLIMID® Patient-Physician Agreement Forms, patient brochure, and survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

- Name
- DEA/Social Security number
- Full address
- Phone number
- Fax number

Patient's:

- Name
- Full address
- Phone number
- Date of birth
- Sex
- Social Security number
- Diagnosis (ICD-9 Code)

- For female patients, you will need to provide information on menstrual and menopause status
- With this information, the Celgene Customer Care Center will generate the applicable form(s) and have them faxed to the number you request

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

Revlimid® (lenalidomide) capsules

For more information about REVLIMID® and RevAssist®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com

Celgene

03/07

REV05065R1

Reference ID: 3128570

RevAssist®

Instructions for Prescribers

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

Special Prescribing Requirements

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID® (lenalidomide), REVLIMID® (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED "REVASSIST®". UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID® (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE REVASSIST® PROGRAM.

2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID® (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY PRESCRIBED IN CONJUNCTION WITH REVLIMID® (lenalidomide) MAY LESSEN THE POTENTIAL FOR VENOUS THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT'S UNDERLYING RISK FACTORS.

You can get the information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll free number 1-888-423-5436.

Revlimid®
(lenalidomide) capsules

About REVLIMID® (lenalidomide)

REVLIMID® in combination with dexamethasone is indicated for the treatment of multiple myeloma patients 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 associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID® should not be used by pregnant women or women capable of becoming pregnant. When there is no alternative, females of childbearing 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 (DVT) and pulmonary embolism (PE) in patients with multiple myeloma 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 reduce the risk of thromboembolic events. The decision to take preventive measures should be done carefully after an assessment of an individual patient's underlying risk factors.

Patients should be advised to read the Medication Guide distributed by the pharmacist at the time REVLIMID® is dispensed.

The RevAssist® Program

REVLIMID® (lenalidomide) is an analogue of thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Females should be advised to avoid pregnancy while taking REVLIMID®.

To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called "RevAssist®." Only prescribers registered with RevAssist® can prescribe REVLIMID® and only RevAssist® contract pharmacies can dispense REVLIMID®. In order to receive REVLIMID®, patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program. Information about REVLIMID® and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com.

Key Features of the RevAssist® Program for Healthcare Providers

- The RevAssist® program tracks critical program components that control access to REVLIMID®
- Only prescribers registered with RevAssist® can prescribe REVLIMID®
- Only patients who are registered in the RevAssist® program can receive REVLIMID®
- Prescribers must counsel patients on the benefits and risks of REVLIMID® therapy in order for patients to be eligible to receive a prescription
- Prescribers must require female patients of childbearing potential to use 2 forms of contraceptives (refer to page 9)
- Prescribers must verify negative pregnancy test results, and RevAssist® contract pharmacies must confirm negative pregnancy test results
- Prescribers must instruct male patients to always use a latex condom every time they have sexual intercourse with a woman who is or can get pregnant, even if they have undergone a successful vasectomy
- Only RevAssist® contract pharmacies can dispense REVLIMID®
- Pharmacists must access the RevAssist® system to receive confirmation to dispense every REVLIMID® prescription

Accessing the RevAssist® System

Prescribers can access the RevAssist® System by calling the Celgene Customer Care Center at 1-888-423-5436.

To access the RevAssist® System by computer, you must:

- Insert computer software (CD-ROM)
- Install program for REVLIMID® Patient-Physician Agreement Form and REVLIMID® Patient Prescription Form (one time only)

For additional assistance regarding REVLIMID® (lenalidomide) and RevAssist®, please contact the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com.

You can also contact your Celgene Hematology Oncology Consultant for more information about REVLIMID® and RevAssist®.

RevAssist® Program Materials

RevAssist® Prescriber Resources (1 per registered prescriber)

- Software CD-ROM with User Guide for REVLIMID® Patient-Physician Agreement Form and REVLIMID® Patient Prescription Form
- RevAssist® At-A-Glance
- Prescriber Guide to English and non-English Materials
- Instructions for Prescribers
- REVLIMID® Patient Chart Sticker for each chart (located on Patient Resource Pack)
- Full Prescribing Information for REVLIMID® (lenalidomide)

RevAssist® System Set-up for Prescribers

- Insert computer software (CD-ROM)
- Install program for REVLIMID® Patient-Physician Agreement Form and REVLIMID® Patient Prescription Form (one time only)
- For additional assistance regarding RevAssist®, please contact your Celgene Hematology Oncology Consultant or the Celgene Customer Care Center toll-free at 1-888-423-5436

RevAssist® Patient Resource Pack (1 per patient)

- RevAssist® Guide to Patient Surveys
- Important Information for Men and Women Taking REVLIMID® (lenalidomide) Brochure
- Emergency Contraception Brochure
- FDA-approved MEDICATION GUIDE

RevAssist® Prescriber Registration

All prescribers MUST be registered to prescribe REVLIMID® (lenalidomide). Completing the Prescriber Registration is required for RevAssist® registration. Please review the steps below that MUST be followed with every patient.

When prescribing REVLIMID®, I agree to:

- Provide patient counseling on the benefits and risks of REVLIMID® therapy, including Boxed WARNINGS
- Provide contraception and emergency contraception counseling in addition to scheduled pregnancy testing for females of childbearing potential
- Submit a completed REVLIMID® Patient-Physician Agreement Form for each new patient to the Celgene Customer Care Center via fax to 1-888-432-9325 or via mail
- Facilitate patient compliance with a mandatory telephone survey
- Complete a brief prescriber telephone survey and obtain a new authorization number for each prescription written
- Provide authorization number on every prescription
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact RevAssist® contract pharmacy to fill the prescription
- Return to Celgene all REVLIMID® that is returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call 1-888-423-5436

How to Fill a REVLIMID® (lenalidomide) Prescription


REVLIMID® (lenalidomide) Patient Prescription Form

- Healthcare provider (HCP) instructs patient to complete patient survey
- HCP completes survey
- HCP completes patient prescription form
- HCP obtains RevAssist® authorization number
- HCP provides authorization number on patient prescription form
- HCP faxes form, including prescription, to one of the RevAssist® contract pharmacies (see REVLIMID® Patient Prescription Form for a list of RevAssist® contract pharmacies)
- HCP advises patient that a representative from a RevAssist® contract pharmacy will contact them
- RevAssist® contract pharmacy conducts patient education
- RevAssist® contract pharmacy calls for confirmation number
- RevAssist® contract pharmacy ships REVLIMID® to patient with the FDA-approved MEDICATION GUIDE

RevAssist® Patient Registration

- Generate, print, and complete the REVLIMID® Patient-Physician Agreement Form
- **Write only in the designated areas on the REVLIMID® Patient-Physician Agreement Form**
  - Patient, parent/legal guardian, and/or authorized representative must read the REVLIMID® Patient-Physician Agreement Form in the language of their choice (available in 16 languages through the Celgene Customer Care Center at 1-888-423-5436)
  - **Each statement must be initialed by the patient to indicate understanding**
  - **The form must be completed and signed by both prescriber and patient**
  - If the patient is under 18 years of age, his or her legal guardian must read this material, initial the statements, sign the form, and agree to ensure compliance

— For an incompetent adult patient, an authorized representative must sign the REVLIMID® Patient-Physician Agreement Form. 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, initial the statements, sign the form, and agree to ensure compliance

Along with REVLIMID® Patient-Physician Agreement Form, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center**. This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® 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 RevAssist® and is authorized to consent to treatment with REVLIMID® (lenalidomide) on behalf of the patient

- Fax the completed REVLIMID® Patient-Physician Agreement Form to the Celgene Customer Care Center at 1-888-432-9325
  — A confirmation letter will be faxed to your office once the patient is registered. In the event that you do not receive this confirmation letter, call the Celgene Customer Care Center at 1-888-423-5436

Note: If therapy with REVLIMID® is discontinued for 12 consecutive months, the patient must register again in the RevAssist® Program. Follow the above procedures to re-register the patient.

RevAssist® Requirements for Patients

Initial REVLIMID® prescriptions

All patients

- Provide comprehensive counseling on the benefits and risks of therapy with REVLIMID®
  — Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with REVLIMID®
- 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
- Provide counseling not to share drugs, not to donate blood, and on appropriate contraceptive use, including counseling on emergency contraception
- Use the patient education materials provided in the RevAssist® Patient Resource Pack

Female patients

Two categories:

1. Females of childbearing potential are all females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal
2. Females NOT of childbearing potential include females who have been postmenopausal naturally for at least 24 consecutive months, or had a hysterectomy or bilateral oophorectomy

For female patients of childbearing potential:

- Female patients must thoroughly understand the need for 2 of the recommended forms of birth control beginning at least 4 weeks before therapy, during therapy, including any necessary dose interruptions, and for at least 4 weeks following discontinuation of therapy with REVLIMID®

- Contraceptive methods must include:
  - At least 1 highly effective method (eg, intrauterine device [IUD], hormonal [birth control pills, injections, hormonal patches or rings or implants], tubal ligation, or partner's vasectomy)
  - AND 1 additional effective barrier method (eg, latex condom, diaphragm or cervical cap)
  - Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with REVLIMID® (lenalidomide)
- Patients should be counseled that concomitant use of certain prescription drugs and/or herbal supplements can decrease the effects of hormonal contraception. During periods of concomitant use, and for 1 month after, 2 barrier methods must be used
- Obtain a negative pregnancy test within 10 to 14 days and 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 be repeated every month 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 fetal exposure to REVLIMID® must be reported immediately to the FDA via the MedWatch number at 1-800-FDA-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

For female patients NOT of childbearing potential:

- The patient certifies that she is not now pregnant, nor of childbearing potential as she has been postmenopausal naturally for at least 24 months, had a hysterectomy or bilateral oophorectomy
- The parent or guardian certifies that a prepubertal female child is not now pregnant, nor is of childbearing 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® therapy, during REVLIMID® therapy, during therapy interruption and for at least 4 weeks after stopping therapy

Male patients

- Male patients must be instructed to always use a latex condom every time they have sexual intercourse with a woman who is or can get pregnant, even if they have undergone a successful vasectomy. The risk to the fetus from the semen of male patients taking lenalidomide is unknown
- Provide counseling not to share drugs, not to donate blood or sperm, and on contraceptive use, including counseling on emergency contraception

Completing telephone survey

- Instruct the patient to complete a brief telephone survey by calling 1-888-423-5436
  - For all males, the REVLIMID® Patient-Physician Agreement Form is considered the initial telephone survey
- Prescriber will complete a brief telephone survey by calling 1-888-423-5436 for every patient before each prescription is written
  - An authorization number will be issued upon completion of the survey and must be written on the prescription. This authorization number and prescription are valid for 7 days for females of childbearing potential and 14 days for all other patients
  - Write authorization number on the prescription

Additional information for prescriber

- Healthcare provider must fax prescription to RevAssist® contract pharmacy
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

Subsequent REVLIMID® (lenalidomide) prescriptions

The prescriber must complete a brief telephone survey to obtain a new authorization number EVERY TIME a prescription for REVLIMID® is written.

Female patients:

- Repeat counseling as outlined above in the Female Patients section
- Follow pregnancy test requirements as outlined above in Female Patients section
- Female patients must complete a brief telephone survey according to the following schedule:
  - Monthly
    - Adult females of childbearing potential
    - All female children
  - Every 6 months
    - Adult females not of childbearing potential

Male patients:

- Provide patient counseling as outlined above in the Male Patients section
- Male patients must complete a brief telephone survey once a month

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

Requirements for Pharmacists

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

- Dispensing pharmacists must be educated on the RevAssist® program and on dispensing procedures for REVLIMID® capsules
- Only accept prescriptions with an authorization number. Authorization numbers and prescriptions are valid for 7 days for females of childbearing potential and 14 days for all other patients. Telephone prescriptions are not permitted
- Call each unique authorization number on every prescription into the automated system at the Celgene Customer Care Center at 1-888-423-5436
  - Enter NABP number or DEA number
  - Enter authorization number written on prescription
  - Enter number of capsules and milligram (mg) strength being dispensed
- If you do not obtain a confirmation number, do not dispense REVLIMID®. Contact the patient's physician and Celgene for further instruction
- Write the confirmation number on the prescription. This confirmation number is only valid for 24 hours
- Provide patient counseling per the RevAssist® program requirements
- Dispense no more than a 4-week (28-day) supply with the FDA-approved MEDICATION GUIDE. A new prescription is required for further dispensing
- **DISPENSE SUBSEQUENT PRESCRIPTIONS ONLY IF FEWER THAN 7 DAYS OF THERAPY REMAIN ON THE PREVIOUS PRESCRIPTION**

If you have any questions, please call the Celgene Customer Care Center at 1-888-423-5436.

RevAssist®

RevAssist® Education and Counseling Checklist Used By RevAssist® Contract Pharmacy

Before a RevAssist® contract pharmacy fills a REVLIMID® (lenalidomide) prescription, the following checklist must be completed. Please use the checklist that applies to the patient risk category written on the front of the Patient Prescription Form.

Checklist for females of childbearing potential

I counseled adults and children on:

- ❑ Potential fetal harm
- ❑ Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse
- ❑ Continuation of 2 forms of birth control if therapy is interrupted and for 4 weeks after therapy is discontinued
- ❑ Obtain a pregnancy test 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, testing should occur every 2 weeks
- ❑ The need to stop taking REVLIMID® right away in the event of becoming pregnant and to call their healthcare provider immediately. Female partners of males taking REVLIMID® must call their healthcare provider right away if they get pregnant
- ❑ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- ❑ Reminder 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 medication
- ❑ Not donating blood while taking REVLIMID® and for 4 weeks after stopping REVLIMID®
- ❑ Not to break, chew, or open REVLIMID® capsules
- ❑ Instructions on REVLIMID® dose and administration: Dose_____ # of Capsules Dispensed_____

Female children (<18 years of age)

- ❑ Parent or legal guardian must have read the RevAssist® education material and agreed to ensure compliance

Checklist for females NOT of childbearing potential (natural menopause for at least 24 consecutive months, a hysterectomy, or bilateral oophorectomy)

I counseled adults and children on:

- ❑ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- ❑ Reminder 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 medication
- ❑ Not donating blood while taking REVLIMID® and for 4 weeks after stopping REVLIMID®
- ❑ Not to break, chew, or open REVLIMID® capsules
- ❑ Instructions on REVLIMID® dose and administration: Dose_____ # of Capsules Dispensed_____

Female children (<18 years of age)

- ❑ Parent or legal guardian must have read the RevAssist® education material and agreed to ensure compliance
- ❑ Must inform their physician when they begin menses

Checklist for males

I counseled adults and children on:

- ❑ Potential fetal harm and contraception (wearing a latex condom when engaging in sexual intercourse with a female of childbearing potential)
- ❑ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- ❑ Reminder 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 medication
- ❑ Not donating blood or sperm while taking REVLIMID® and for 4 weeks after stopping REVLIMID®
- ❑ Not to break, chew, or open REVLIMID® capsules
- ❑ Instructions on REVLIMID® dose and administration: Dose_____ # of Capsules Dispensed_____

Male children (<18 years of age)

❑ Parent or legal guardian must have read the RevAssist® education material and agreed to ensure compliance

DO NOT dispense or ship REVLIMID® (lenalidomide) to a patient unless all the following are done:

- Prescription has an authorization number
- You have counseled the patient
- You have obtained a confirmation number
- You are shipping the product within 24 hours of obtaining the confirmation number
- The FDA-approved MEDICATION GUIDE is included with the prescription
- You confirm the prescription is no more than a 28-day supply and there are 7 days or less remaining on an existing REVLIMID® prescription

Determine Childbearing Potential of Female Patients

Qualification criteria

Female patients of childbearing potential

- Sexually mature females who have not undergone a hysterectomy, bilateral oophorectomy, or who have not been postmenopausal naturally for at least 24 consecutive months (i.e., who have had menses at some time in the preceding 24 consecutive months) are considered to be females of childbearing potential

Female patients NOT of childbearing potential

- Sexually mature females who are not now pregnant, nor of childbearing potential, who have been postmenopausal naturally for at least 24 months (been through the change of life); or have had a hysterectomy or bilateral oophorectomy

Effective forms of contraception

Primary forms	Secondary forms
• Intrauterine device (IUD)	• Male latex condom
• Tubal ligation	• Diaphragm
• Partner's vasectomy	• Cervical cap
• Hormonal birth control pills, patch, injections, implants, or ring	

Unacceptable forms of contraception

- Progesterone-only "mini-pills," e.g.:
  - Ortho Micronor® Tablets*
  - Ovrette® Tablets†
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield‡

*Ortho Micronor® is a registered trademark of Ortho-McNeil Pharmaceutical, Inc.

† Ovrette is a registered trademark of Wyeth Pharmaceuticals Inc.

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

RevAssist®

Contraception counseling

Ensure that every female patient of childbearing potential receives adequate counseling about all her pregnancy prevention options (including abstinence) and that she knows how to select and use 2 separate and effective forms of contraception.

Ensure every male patient is instructed to always use a latex condom every time he has sexual intercourse with a woman who is or can get pregnant, even if he has undergone a successful vasectomy.

After the Last Dose

- **Do not get pregnant while taking REVLIMID®** (lenalidomide) and for 4 weeks after stopping REVLIMID®
- **Do not give blood while you take REVLIMID®** and for 4 weeks after stopping REVLIMID®. If someone who is pregnant gets your donated blood, her baby may be exposed to REVLIMID® and may be born with birth defects
- **Male patients should not donate sperm** while taking REVLIMID® and for 4 weeks after stopping REVLIMID®. If a female who is trying to become pregnant gets your sperm, her baby may be exposed to REVLIMID® and may be born with birth defects

In the Event of Pregnancy

- 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. REVLIMID® treatment must be discontinued during this evaluation
- Any suspected 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 patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

If you get pregnant while taking REVLIMID®, stop taking it right away and call your healthcare provider. Female partners of males taking REVLIMID® must call their healthcare provider right away if they get pregnant. Healthcare providers and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- Celgene Corporation at 1-888-423-5436

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

RevAssist®

RevAssist®

For more information about REVLIMID® and RevAssist®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com

Revlimid®
(lenalidomide) capsules

03/07

REV05070R1

RevAssist® program for REVLIMID®
education and prescribing safety

RevAssist®
Patient Resource Pack

The Patient Resource Pack contains:

- RevAssist® Guide to Patient Surveys
- Important Information for Men and Women Taking REVLIMID® (lenalidomide) brochure
- Emergency Contraception brochure
- The FDA-approved MEDICATION GUIDE
  — Each patient must receive the MEDICATION GUIDE with each prescription dispensed

Revlimid®
(lenalidomide) capsules

Detach and affix to patient chart

RevAssist®

Patient registration date: _____

Prescriber:

- Instruct the patient to complete a survey (check one):
  - ❒ monthly ❒ every 6 months
- Complete prescriber survey with every prescription

Date of Visit	Date of CBC	Date of Pregnancy Test (if applicable)	Prescriber Survey	Patient Survey*

* As described in Instructions for Prescribers.

1-888-423-5436

www.REVLIMID.com

Evaluate your del 5q MDS patients closely for cytopenias:

Del 5q MDS patients should have their complete blood counts monitored weekly for the first 8 weeks of therapy, and at least monthly thereafter.

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

Revlimid® (lenalidomide) capsules

RevAssist®

Important Information for Men and Women Taking REVLIMID® (lenalidomide)

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

Special Prescribing Requirements

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID® (lenalidomide), REVLIMID® (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED "REVASSIST®". UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID® (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE REVASSIST® PROGRAM.

2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID® (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY PRESCRIBED IN CONJUNCTION WITH REVLIMID® (lenalidomide) MAY LESSEN THE POTENTIAL FOR VENOUS THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT'S UNDERLYING RISK FACTORS.

You can get the information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll free number 1-888-423-5436.

Revlimid®
(lenalidomide) capsules

If you or someone you know has been prescribed REVLIMID® (lenalidomide), read this brochure to learn more about REVLIMID® and the RevAssist® program

What is RevAssist®?

- To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called "RevAssist®"
- Only prescribers registered with RevAssist® can prescribe REVLIMID® (lenalidomide)
- Only RevAssist® contract pharmacies can dispense REVLIMID® (lenalidomide)
- In order to receive REVLIMID® (lenalidomide), patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program
- Information about REVLIMID® (lenalidomide) and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com

What do all patients need to know about RevAssist®?

General guidelines

- This medicine is ONLY for you. DO NOT SHARE IT WITH ANYONE, even someone who has symptoms like yours. It must be kept out of the reach of children and should never be given to women who are able to become pregnant
- Keep REVLIMID® in a cool, dry place
- Do NOT donate blood or sperm while you are being treated with REVLIMID®

The following sections outline important information for all female and male patients.

What do female patients of childbearing potential need to know for the RevAssist® program?

A. Before your REVLIMID® (lenalidomide) treatment

- ❑ You must sign the REVLIMID® 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 begin 2 methods of birth control 4 weeks BEFORE you start taking REVLIMID®
- ❑ Your healthcare provider must give you a pregnancy test within 10–14 days and again within 24 hours before the prescription for REVLIMID® is written. If you are pregnant, you cannot take REVLIMID®
- ❑ You will have pregnancy tests before and during treatment, even if you agree not to have sexual intercourse with a man
- ❑ Before your healthcare provider can write your prescription for REVLIMID®, you must take part in a mandatory, confidential survey. The survey will help ensure that you received, understand, and can follow information designed to prevent fetal exposure
- ❑ You must discuss your treatment with your RevAssist® contract pharmacy

1. Choose 2 forms of birth control

You should discuss with your healthcare provider information given to you about the following acceptable birth control methods:

Highly effective methods

- Intrauterine device (IUD)
- Hormonal (birth control pills, patch, injections, implants, or ring)
- Tubal ligation
- Partner's vasectomy

Additional effective methods

- Latex condom
- Diaphragm
- Cervical cap

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

Remember: You must use at least 1 highly effective method and 1 additional effective method AT THE SAME TIME. However, your healthcare provider may recommend that you use 2 barrier methods for medical reasons.

REMEMBER THAT THE ONLY METHOD OF BIRTH CONTROL THAT IS 100% EFFECTIVE IS NOT HAVING ANY SEXUAL INTERCOURSE AT ALL.

3. Unacceptable forms of contraception

- Progesterone-only "mini-pills," e.g.:
  - Ortho Micronor® Tablets*
  - Ovrette® Tablets†
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield‡

4. Get tests for pregnancy

You must have a pregnancy test done by your healthcare provider within 10–14 days and again within 24 hours before you are prescribed REVLIMID®.

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†Ovrette is a registered trademark of Wyeth Pharmaceuticals Inc.

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

B. During treatment

- ❑ If you are able to have children, you must continue to use 2 methods of birth control, as discussed with your healthcare provider, during treatment and through any necessary dose interruptions
- ❑ 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 weekly during the first 4 weeks, then every 4 weeks, if your menstrual cycles are regular, or every 2 weeks if your cycles are irregular. You may also need to have a pregnancy test if you miss your period or have unusual menstrual bleeding
- ❑ For women who may become pregnant and who have had sexual intercourse without using birth control, stop taking REVLIMID® (lenalidomide) immediately and talk to your healthcare provider
- ❑ If you get pregnant, you must IMMEDIATELY stop taking REVLIMID®. 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
- ❑ You must not breastfeed a baby while you are being treated with REVLIMID®
- ❑ You must NEVER donate blood while you are being treated with REVLIMID®
- ❑ In order to continue receiving REVLIMID®, you must periodically take part in a mandatory, confidential survey as scheduled and continue to discuss your treatment with your RevAssist® contract pharmacy. To take the survey, please call the Celgene Customer Care Center at 1-888-423-5436
- ❑ REMEMBER THAT THE ONLY METHOD OF BIRTH CONTROL THAT IS 100% EFFECTIVE IS NOT HAVING ANY SEXUAL INTERCOURSE AT ALL

C. After treatment ends

- ❑ You must continue to use the same 2 methods of birth control for 4 weeks after you receive your last dose of REVLIMID® (lenalidomide), or abstain from any sexual intercourse
- ❑ You must NOT donate blood for 4 weeks after receiving your last dose of REVLIMID®

What do female patients not of childbearing potential need to know for the RevAssist® program?

- ❑ You must sign the REVLIMID® Patient-Physician Agreement Form that says you are presently not pregnant and do not have the ability to have children. This means that you have been postmenopausal naturally for at least 24 months, had a hysterectomy, or had a bilateral oophorectomy
- ❑ For prepubertal females, a parent or guardian must sign the REVLIMID® Patient-Physician Agreement Form that says the patient is presently not pregnant, is not able to get pregnant, and/or will not be engaging in heterosexual sexual contact for at least 4 weeks before therapy, during therapy, during therapy interruption, and for at least 4 weeks after stopping therapy

What do male patients need to know for the RevAssist® program?

You must use a latex condom (even if you have had a vasectomy) every time you have sexual intercourse with a female who is of childbearing potential.

A. Before your REVLIMID® (lenalidomide) treatment

- ❑ You must sign the REVLIMID® Patient-Physician Agreement Form that says you understand that while taking REVLIMID® you must use a latex condom every time you have sexual intercourse with a female who is able to get pregnant

B. During treatment

- ❑ You must take a monthly, mandatory confidential survey to ensure that you received, understood, and can follow information on preventing fetal exposure. To take the survey, please call the Celgene Customer Care Center at 1-888-423-5436
- ❑ You must use a latex condom (even if you have had a vasectomy) EVERY TIME you have sexual intercourse with a female who is able to get pregnant
- ❑ You must tell your healthcare provider if you have sexual intercourse with a female without using a latex condom, or if you think for any reason that your partner may be pregnant
- ❑ You must NOT donate blood or sperm while you are taking REVLIMID®
- ❑ REMEMBER THAT THE ONLY METHOD OF BIRTH CONTROL THAT IS 100% EFFECTIVE IS NOT HAVING ANY SEXUAL INTERCOURSE AT ALL

C. After treatment ends

- ❑ You must use a latex condom (even if you have had a vasectomy) EVERY TIME you have sexual intercourse with a female who can get pregnant for 4 weeks after receiving your last dose of REVLIMID® (lenalidomide)
- ❑ You must NOT donate blood or sperm for 4 weeks after receiving your last dose of REVLIMID®

Warning to patients taking REVLIMID®

Attention Women:

Do NOT take REVLIMID® if you are pregnant, if you are breastfeeding, or if you are able to become pregnant and are not using the required 2 forms of birth control.

Attention Men:

You must use a latex condom (even if you have had a vasectomy) EVERY TIME you have sexual intercourse with a woman of childbearing potential.

Attention All Patients:

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

RevAssist®

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

Revlimid®
(lenalidomide) capsules

REVLIMID® Patient-Physician Agreement Form

Adult Male

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

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Special Prescribing Requirements

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2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

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3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

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You can get information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll-free number at 1-888-423-5436.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Male

For more information please see the REVLIMID® Medication Guide.

Patient/Authorized Representative: Please read thoroughly and initial inside of the box provided, if you agree with the statement. Please keep a copy of this Patient-Physician Agreement Form for your records.

	Initial
1. I understand that birth defects may occur with the use of REVLIMID® (lenalidomide). I have been warned by my doctor that any unborn baby may have birth defects and can even die if a female is pregnant or becomes pregnant while taking REVLIMID® (lenalidomide).	☐
2. I have been told by my doctor that I must NEVER have unprotected sexual contact with a female who can become pregnant. Because it is known that REVLIMID® (lenalidomide) is present in semen, my doctor has explained that I must either completely abstain from sexual contact with females who are pregnant or able to become pregnant, or I must use a latex condom EVERY TIME I engage in any sexual contact with females who are pregnant or may become pregnant while taking REVLIMID® (lenalidomide) - and for 4 weeks after I stop taking the drug, even if I have had a successful vasectomy.	☐
3. I know that I must inform my doctor if I have had unprotected sexual contact with a female who can become pregnant; or if I think, FOR ANY REASON, that my sexual partner may be pregnant. If my doctor is not available, I can call 1-888-668-2528 for information on emergency contraception.	☐
4. I understand that REVLIMID® (lenalidomide) will be prescribed ONLY for me. I must not share it with ANYONE, even someone who has similar symptoms to mine. It must be kept out of the reach of children and should NEVER be given to females who are able to have children.	☐
5. I agree any unused drug will be returned to Celgene by calling 1-888-423-5436. Shipping costs will be paid by Celgene. I understand that Celgene cannot provide patients with a refund for the unused drug.	☐
6. I have read the REVLIMID® (lenalidomide) patient brochure. I understand the contents, including other possible health problems or "side effects" from REVLIMID® (lenalidomide). I know that I cannot donate blood or semen while taking REVLIMID® (lenalidomide) or for 4 weeks after stopping REVLIMID® (lenalidomide).	☐
7. I understand that I must participate in a telephone survey and patient registry while I am on REVLIMID® (lenalidomide).	☐
8. My doctor has answered any questions I have asked.	☐
9. I understand that I might be asked to participate in an additional voluntary survey by mail or telephone to evaluate this RevAssist® program. My agreement or disagreement will not interfere with my ability to receive REVLIMID® (lenalidomide).	☐
10. I acknowledge I may be contacted by a Celgene representative in regards to following the rules of the RevAssist® program.	☐

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Male

Authorization:
I understand that by signing this Authorization, I permit my healthcare providers and pharmacies to disclose to Celgene Corporation, its agents and contractors, my medical and other health information for the following purposes:

(a) coordinate the delivery of products and services available through pharmacies and Celgene's patient assistance programs;
(b) conduct data analyses regarding the use of REVLIMID® (lenalidomide);
(c) comply with applicable law;
(d) provide me with information regarding REVLIMID® (lenalidomide).

I understand that I may be contacted by Celgene or its agents and asked if I am willing to voluntarily answer additional survey questions that will help to evaluate RevAssist®.

This Authorization will be effective for 12 months after the date on which I stop receiving REVLIMID® (lenalidomide). However it may be revoked earlier, at any time, by me informing my healthcare provider that I will no longer participate in RevAssist®.

I understand that once my information is disclosed, there is no guarantee that the recipient of the information will not re-disclose it, and the recipient may not be required to abide by this Authorization.

I understand that I may refuse to sign this Authorization. Such refusal constitutes a refusal to participate in RevAssist®, and will affect my ability to receive REVLIMID® (lenalidomide).

I understand that I may refuse to participate in the voluntary survey. My refusal to participate in the survey will not change how my healthcare providers and pharmacies provide my medical treatment, and will not affect my ability to receive REVLIMID® (lenalidomide).

Yes_____ No_____ I authorize the information disclosure as described above.

Yes_____ No_____ I agree to participate in the voluntary survey described above.

UPON SIGNING THIS AUTHORIZATION, PATIENT HAS THE RIGHT TO OBTAIN A COPY, UPON REQUEST.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Male

This information has been read aloud to me in the language of my choice. I understand that if I do not follow all of my doctor's instructions, I will not be able to receive REVLIMID® (lenalidomide). I also understand that the information I provide on this Patient-Physician Agreement Form and as part of ongoing surveys will be known by the manufacturer of REVLIMID® (lenalidomide) and the FDA. However, the information will not be used for commercial purposes.

The below party now authorizes my doctor to begin treatment with REVLIMID® (lenalidomide).

Date:	01-May-2007
Patient Name:	DOE, JOHN
Address:	1 MAIN STREET, SUMMIT, NJ 07901
Telephone Number:	111-111-1111
Social Security No:	123-45-7890
Date of Birth:	01-Jan-1940
Sex:	M
ICD-9 Diagnosis Code:	238.7 MDS: MYELODYSPLASTIC SYNDROMES

Patient/Authorized Representative Signature: _____

Date: _____

I have fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females of childbearing potential. I have asked the patient if he has any questions regarding his treatment with REVLIMID® (lenalidomide) and have answered those questions to the best of my ability. I will comply with all of my obligations and responsibilities as a prescriber registered under RevAssist®.

Prescriber Name:	DOE, MARK
DEA Number:	AD1234567
Social Security No:	--
Address:	11 MAIN ST, SUMMIT, NJ 07901
Telephone Number:	111-111-1234
Fax Number:	111-111-1111

Prescriber Signature: _____

Date: _____

FAX THIS FORM TO 1-888-432-9325

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Male Child

WARNINGS:

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AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Male Child

For more information please see the REVLIMID® Medication Guide.

Parent/Guardian: Please read thoroughly and initial inside of the box provided, if you agree with the statement. Please keep a copy of this Patient-Physician Agreement Form for your records.

	Initial
1. I understand that birth defects may occur with the use of REVLIMID® (lenalidomide). I have been warned by my child's doctor that any unborn baby may have birth defects and can even die if a female is pregnant or becomes pregnant while taking REVLIMID® (lenalidomide).	☐
2. I have been told by my child's doctor that the child in my care must NEVER have unprotected sexual contact with a female who can become pregnant. Because it is known that REVLIMID®(lenalidomide) is present in semen, my child's doctor has explained that he must either completely abstain from sexual contact with females who are pregnant or able to become pregnant or must use a latex condom EVERY TIME he engages in any sexual contact with females who are pregnant or able to become pregnant while taking REVLIMID® (lenalidomide) - and for 4 weeks after he stops taking the drug.	☐
3. I also know that I must inform his doctor if he has unprotected sexual contact with a female who can become pregnant; or if I think, FOR ANY REASON, that his sexual partner may be pregnant. If his doctor is not available, I can call 1-888-668-2528 for information on emergency contraception.	☐
4. I understand that REVLIMID® (lenalidomide) will be prescribed ONLY for the child in my care. It must not be shared with ANYONE, even someone who has similar symptoms to the child in my care. It must be kept out of the reach of children and should NEVER be given to females who are able to have children.	☐
5. I agree any unused drug will be returned to Celgene by calling 1-888-423-5436. Shipping costs will be paid by Celgene. I understand that Celgene cannot provide patients with a refund for the unused drug.	☐
6. I have read the REVLIMID® (lenalidomide) patient brochure. I understand the contents, including other possible health problems or "side effects" from REVLIMID® (lenalidomide). I know that he cannot donate blood or semen while taking REVLIMID® (lenalidomide) or for 4 weeks after stopping REVLIMID® (lenalidomide).	☐
7. I understand that we must participate in a telephone survey and patient registry while the child in my care is taking REVLIMID® (lenalidomide).	☐
8. Our doctor has answered any questions that we have asked.	☐
9. I understand that we might be asked to participate in an additional voluntary survey by mail or telephone to evaluate the RevAssist® program. Our agreement or disagreement will not interfere with my child's ability to receive REVLIMID® (lenalidomide).	☐
10. I acknowledge that we may be contacted by a Celgene representative in regards to the RevAssist® program.	☐

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Male Child

Authorization:
I understand that by signing this Authorization, I permit my healthcare providers and pharmacies to disclose to Celgene Corporation, its agents and contractors, my medical and other health information for the following purposes:

(a) coordinate the delivery of products and services available through pharmacies and Celgene's patient assistance programs;
(b) conduct data analyses regarding the use of REVLIMID® (lenalidomide);
(c) comply with applicable law;
(d) provide me with information regarding REVLIMID® (lenalidomide).

I understand that I may be contacted by Celgene or its agents and asked if I am willing to voluntarily answer additional survey questions that will help to evaluate RevAssist®.

This Authorization will be effective for 12 months after the date on which I stop receiving REVLIMID® (lenalidomide). However it may be revoked earlier, at any time, by me informing my healthcare provider that I will no longer participate in RevAssist®.

I understand that once my information is disclosed, there is no guarantee that the recipient of the information will not re-disclose it, and the recipient may not be required to abide by this Authorization.

I understand that I may refuse to sign this Authorization. Such refusal constitutes a refusal to participate in RevAssist®, and will affect my ability to receive REVLIMID® (lenalidomide).

I understand that I may refuse to participate in the voluntary survey. My refusal to participate in the survey will not change how my healthcare providers and pharmacies provide my medical treatment, and will not affect my ability to receive REVLIMID® (lenalidomide).

Yes_____ No_____ I authorize the information disclosure as described above.

Yes_____ No_____ I agree to participate in the voluntary survey described above.

UPON SIGNING THIS AUTHORIZATION, PATIENT HAS THE RIGHT TO OBTAIN A COPY, UPON REQUEST.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Male Child

This information has been read aloud to us in the language of our choice. I understand that if we do not follow all of our doctor's instructions, the child in my care will not be able to receive REVLIMID® (lenalidomide). I also understand that the information we provide on this Patient-Physician Agreement Form and as part of ongoing surveys will be known by the manufacturer of REVLIMID® (lenalidomide) and the FDA. However, the information will not be used for commercial purposes.

The below party now authorizes my child's doctor to begin treating the child in my care with REVLIMID® (lenalidomide).

Date:	01-May-2007
Patient Name:	DOE, JOHN
Address:	1 MAIN STREET, SUMMIT, NJ 07901
Telephone Number:	111-111-1111
Social Security No:	123-45-7890
Date of Birth:	01-Jan-1990
Sex:	M
ICD-9 Diagnosis Code:	238.7 MDS: MYELODYSPLASTIC SYNDROMES

Parent/Guardian Signature: _____

Date: _____

I have fully explained to the parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females of childbearing potential. I have asked the parent/guardian if he/she has any questions regarding the child's treatment with REVLIMID® (lenalidomide) and have answered those questions to the best of my ability. I will comply with all of my obligations and responsibilities as a prescriber registered under RevAssist®.

Prescriber Name:	DOE, MARK
DEA Number:	AD1234567
Social Security No:	--
Address:	11 MAIN ST, SUMMIT, NJ 07901
Telephone Number:	111-111-1234
Fax Number:	111-111-1111

Prescriber Signature: _____

Date: _____

FAX THIS FORM TO 1-888-432-9325

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Female Not of Childbearing Potential

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

Special Prescribing Requirements

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID® (lenalidomide), REVLIMID® (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED "REVASSIST®". UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID® (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE REVASSIST® PROGRAM.

2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID® (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY PRESCRIBED IN CONJUNCTION WITH REVLIMID® (lenalidomide) MAY LESSEN THE POTENTIAL FOR VENOUS THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT'S UNDERLYING RISK FACTORS.

You can get information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll-free number at 1-888-423-5436.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Female Not of Childbearing Potential

For more information please see the REVLIMID® Medication Guide.

Patient/Authorized Representative: Please read thoroughly and initial inside of the box provided if you agree with the statement. Please keep a copy of this Patient-Physician Agreement Form for your records.

	Initial
1. I understand that birth defects may occur with the use of REVLIMID® (lenalidomide). I have been warned by my doctor that any unborn baby may have birth defects and can even die if a female is pregnant or becomes pregnant while taking REVLIMID® (lenalidomide).	☐
2. I certify that I am not now pregnant, nor am I of childbearing potential as I have been in a natural menopause for at least 24 months (been through the changes of life); or I had my uterus/womb completely removed (hysterectomy) or had both of my ovaries removed (bilateral oophorectomy).	☐
3. I understand that REVLIMID® (lenalidomide) will be prescribed ONLY for me. I must not share it with ANYONE, even someone who has similar symptoms to mine. It must be kept out of the reach of children and should NEVER be given to females who are able to have children.	☐
4. I agree any unused drug will be returned to Celgene by calling 1-888-423-5436. Shipping costs will be paid by Celgene. I understand that Celgene cannot provide patients with a refund for the unused drug.	☐
5. I have read the REVLIMID® (lenalidomide) patient brochure. I understand the contents, including other possible health problems or "side effects" from REVLIMID® (lenalidomide). I know that I cannot donate blood while taking REVLIMID® (lenalidomide) or for 4 weeks after stopping REVLIMID® (lenalidomide).	☐
6. I understand that I must participate in a telephone survey and patient registry while I am on REVLIMID® (lenalidomide).	☐
7. My doctor has answered any questions I have asked.	☐
8. I understand that I might be asked to participate in an additional voluntary survey by mail or telephone to evaluate this RevAssist® program. My agreement or disagreement will not interfere with my ability to receive REVLIMID® (lenalidomide).	☐
9. I acknowledge I may be contacted by a Celgene representative in regards to following the rules with the RevAssist® program.	☐

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Female Not of Childbearing Potential

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(a) coordinate the delivery of products and services available through pharmacies and Celgene's patient assistance programs;
(b) conduct data analyses regarding the use of REVLIMID® (lenalidomide);
(c) comply with applicable law;
(d) provide me with information regarding REVLIMID® (lenalidomide).

I understand that I may be contacted by Celgene or its agents and asked if I am willing to voluntarily answer additional survey questions that will help to evaluate RevAssist®.

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I understand that I may refuse to sign this Authorization. Such refusal constitutes a refusal to participate in RevAssist®, and will affect my ability to receive REVLIMID® (lenalidomide).

I understand that I may refuse to participate in the voluntary survey. My refusal to participate in the survey will not change how my healthcare providers and pharmacies provide my medical treatment, and will not affect my ability to receive REVLIMID® (lenalidomide).

Yes_____ No_____ I authorize the information disclosure as described above.

Yes_____ No_____ I agree to participate in the voluntary survey described above.

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AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Female Not of Childbearing Potential

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The below party now authorizes my doctor to begin treatment with REVLIMID® (lenalidomide).

Date:	01-May-2007	No	Yes	Yes

Patient Name: DOE, JANE
Address: 1 MAIN STREET, SUMMIT, NJ 07901
Telephone Number: 111-111-1111
Social Security No: 123-45-7890
Date of Birth: 01-Jan-1942
Sex: F
ICD-9 Diagnosis Code: 238.7 MDS: MYELODYSPLASTIC SYNDROMES

Patient/Authorized Representative Signature: _____
Date: _____

I have fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females of childbearing potential. I have asked the patient if she has any questions regarding her treatment with REVLIMID® (lenalidomide) and have answered those questions to the best of my ability. I will comply with all of my obligations and responsibilities as a prescriber registered under RevAssist®.

Prescriber Name: DOE, MARK
DEA Number: AD1234567
Social Security No: --
Address: 11 MAIN ST, SUMMIT, NJ 07901
Telephone Number: 111-111-1234
Fax Number: 111-111-1111

Prescriber Signature: _____
Date: _____

FAX THIS FORM TO 1-888-432-9325

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Female of Childbearing Potential

WARNINGS:

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You can get information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll-free number at 1-888-423-5436.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Female of Childbearing Potential

For more information please see the REVLIMID® Medication Guide.

Patient/Authorized Representative: Please read thoroughly and initial inside of the box provided, if you agree with the statement. Please keep a copy of this Patient-Physician Agreement Form for your records.

Initial

1. I understand that birth defects may occur with the use of REVLIMID® (lenalidomide). I have been warned by my doctor that my unborn baby may have birth defects and can even die if I am pregnant or become pregnant while taking REVLIMID® (lenalidomide). ☐

2. I understand that I must not take REVLIMID® (lenalidomide) if I am pregnant, breast-feeding a baby, or able to get pregnant and not using the required two methods of birth control. ☐

3. If I am having sexual relations with a man, and I am less than 50 years of age, and/or menses stopped due to treatment of my disease, I understand I am able to become pregnant. I must use at least one highly effective method and one additional effective method of birth control (contraception) AT THE SAME TIME: ☐

At least one highly effective method	**AND**	**One additional effective method**
IUD		Latex condom
Hormonal (birth control pills, injections, patch, implants)		Diaphragm
Tubal ligation (tubes tied)		Cervical cap
Partner's vasectomy		

These birth control methods must be used for at least 4 weeks before starting REVLIMID® (lenalidomide) therapy, all during REVLIMID® (lenalidomide) therapy, during therapy interruption, and for at least 4 weeks after REVLIMID® (lenalidomide) therapy has stopped. I must use these methods unless I completely abstain from heterosexual sexual contact. If a hormonal (birth control pills, injections, patch, or implants) or IUD method is not medically possible for me, I may use another highly effective method or two barrier methods AT THE SAME TIME.

4. I know that I must have a pregnancy test done by my doctor within the 10 to 14 days and 24 hours prior to being prescribed REVLIMID® (lenalidomide), even if I have not had my menses due to treatment of my disease, then every week during the first 4 weeks of REVLIMID® (lenalidomide) therapy. I will then have a pregnancy test every 4 weeks if I have regular and/or no menstrual cycles, or every 2 weeks if my cycles are irregular while I am taking REVLIMID® (lenalidomide). ☐

5. I know that I must immediately stop taking REVLIMID® (lenalidomide) and inform my doctor if I become pregnant while taking the drug, if I miss my menstrual period, or experience unusual menstrual bleeding, stop using birth control, or think, FOR ANY REASON, that I may be pregnant. If my doctor is not available, I can call 1-888-668-2528 for information on emergency contraception. ☐

6. I am not now pregnant, nor will I try to become pregnant for at least 4 weeks after I have completely finished taking REVLIMID® (lenalidomide). ☐

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Adult Female of Childbearing Potential

7. I understand that REVLIMID® (lenalidomide) will be prescribed ONLY for me. I must NOT share it with ANYONE, even someone who has similar symptoms to mine. It must be kept out of the reach of children and should NEVER be given to females who are able to have children. ☐

8. I agree any unused drug will be returned to Celgene by calling 1-888-423-5436. Shipping costs will be paid by Celgene. I understand that Celgene cannot provide patients with a refund for the unused drug. ☐

9. I have read the REVLIMID® (lenalidomide) patient brochure. I understand the contents, including other possible health problems or "side effects" from REVLIMID® (lenalidomide). I know that I cannot donate blood while taking REVLIMID® (lenalidomide) and for 4 weeks after stopping REVLIMID® (lenalidomide). ☐

10. I understand that I must participate in a telephone survey and patient registry while I am on REVLIMID® (lenalidomide). ☐

11. My doctor has answered any questions I have asked. ☐

12. I understand that I might be asked to participate in an additional voluntary survey by mail or telephone to evaluate the RevAssist® program. My agreement or disagreement will not interfere with my ability to receive REVLIMID® (lenalidomide). ☐

13. I acknowledge I may be contacted by a Celgene representative in regards to following the rules with the RevAssist® program. ☐

AD1234567-7890

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Adult Female of Childbearing Potential

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(a) coordinate the delivery of products and services available through pharmacies and Celgene's patient assistance programs;
(b) conduct data analyses regarding the use of REVLIMID® (lenalidomide);
(c) comply with applicable law;
(d) provide me with information regarding REVLIMID® (lenalidomide).

I understand that I may be contacted by Celgene or its agents and asked if I am willing to voluntarily answer additional survey questions that will help to evaluate RevAssist®.

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Yes_____ No_____ I authorize the information disclosure as described above.

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Adult Female of Childbearing Potential

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The below party now authorizes my doctor to begin treatment with REVLIMID® (lenalidomide).

Date:	01-May-2007	Yes	No	No

Patient Name: DOE, JANE
Address: 1 MAIN STREET, SUMMIT, NJ 07901
Telephone Number: 111-111-1111
Social Security No: 123-45-7890
Date of Birth: 01-Jan-1972
Sex: F
ICD-9 Diagnosis Code: 238.7 MDS: MYELODYSPLASTIC SYNDROMES

Patient/Authorized Representative Signature: _____
Date: _____

I have fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females of childbearing potential. I have asked the patient if she has any questions regarding her treatment with REVLIMID® (lenalidomide) and have answered those questions to the best of my ability. I will comply with all of my obligations and responsibilities as a prescriber registered under RevAssist®.

Prescriber Name: DOE, MARK
DEA Number: AD1234567
Social Security No: --
Address: 11 MAIN ST, SUMMIT, NJ 07901
Telephone Number: 111-111-1234
Fax Number: 111-111-1111

Prescriber Signature: _____
Date: _____

FAX THIS FORM TO 1-888-432-9325

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Female Child Not of Childbearing Potential

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

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THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID® (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY PRESCRIBED IN CONJUNCTION WITH REVLIMID® (lenalidomide) MAY LESSEN THE POTENTIAL FOR VENOUS THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT'S UNDERLYING RISK FACTORS.

You can get information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll-free number at 1-888-423-5436.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Female Child Not of Childbearing Potential

For more information please see the REVLIMID® Medication Guide.

Patient/Guardian: Please read thoroughly and initial inside of the box provided, if you agree with the statement. Please keep a copy of this Patient-Physician Agreement Form for your records.

	Initial
1. I understand that birth defects may occur with the use of REVLIMID® (lenalidomide). I have been warned by my child's doctor that any unborn baby may have birth defects and can even die if a female is pregnant or becomes pregnant while taking REVLIMID® (lenalidomide).	☐
2. I certify that the child in my care is not now pregnant, nor is she of childbearing 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 REVLIMID® (lenalidomide) therapy, during therapy interruption, or for at least 4 weeks after stopping therapy.	☐
3. I understand that REVLIMID® (lenalidomide) will be prescribed ONLY for the child in my care. It must not be shared with ANYONE, even someone who has similar symptoms to the child in my care. It must be kept out of the reach of children and should NEVER be given to females who are able to have children.	☐
4. I agree any unused drug will be returned to Celgene by calling 1-888-423-5436. Shipping costs will be paid by Celgene. I understand that Celgene cannot provide patients with a refund for the unused drug.	☐
5. I have read the REVLIMID® (lenalidomide) patient brochure. I understand the contents, including other possible health problems or "side effects" from REVLIMID® (lenalidomide). I know that she cannot donate blood while taking REVLIMID® (lenalidomide) or for 4 weeks after stopping REVLIMID® (lenalidomide).	☐
6. I understand that we must participate in a telephone survey and patient registry while the child in my care is on REVLIMID® (lenalidomide).	☐
7. Our doctor has answered any questions that we have asked.	☐
8. I understand that we might be asked to participate in an additional voluntary survey by mail or telephone to evaluate the RevAssist® program. Our agreement or disagreement will not interfere with my child's ability to receive REVLIMID® (lenalidomide).	☐
9. I acknowledge that we may be contacted by a Celgene representative in regards to my child following the rules with the RevAssist® program.	☐

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Female Child Not of Childbearing Potential

Authorization:
I understand that by signing this Authorization, I permit my healthcare providers and pharmacies to disclose to Celgene Corporation, its agents and contractors, my medical and other health information for the following purposes:

(a) coordinate the delivery of products and services available through pharmacies and Celgene's patient assistance programs;
(b) conduct data analyses regarding the use of REVLIMID® (lenalidomide);
(c) comply with applicable law;
(d) provide me with information regarding REVLIMID® (lenalidomide).

I understand that I may be contacted by Celgene or its agents and asked if I am willing to voluntarily answer additional survey questions that will help to evaluate RevAssist®.

This Authorization will be effective for 12 months after the date on which I stop receiving REVLIMID® (lenalidomide). However it may be revoked earlier, at any time, by me informing my healthcare provider that I will no longer participate in RevAssist®.

I understand that once my information is disclosed, there is no guarantee that the recipient of the information will not re-disclose it, and the recipient may not be required to abide by this Authorization.

I understand that I may refuse to sign this Authorization. Such refusal constitutes a refusal to participate in RevAssist®, and will affect my ability to receive REVLIMID® (lenalidomide).

I understand that I may refuse to participate in the voluntary survey. My refusal to participate in the survey will not change how my healthcare providers and pharmacies provide my medical treatment, and will not affect my ability to receive REVLIMID® (lenalidomide).

Yes_____ No_____ I authorize the information disclosure as described above.

Yes_____ No_____ I agree to participate in the voluntary survey described above.

UPON SIGNING THIS AUTHORIZATION, PATIENT HAS THE RIGHT TO OBTAIN A COPY, UPON REQUEST.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Female Child Not of Childbearing Potential

This information has been read aloud to us in the language of our choice. I understand that if we do not follow all of our doctor's instructions, the child in my care will not be able to receive REVLIMID® (lenalidomide). I also understand that the information we provide on this Patient-Physician Agreement Form and as part of ongoing surveys will be known by the manufacturer of REVLIMID® (lenalidomide) and the FDA. However, the information will not be used for commercial purposes.

The below party now authorizes my child's doctor to begin treating the child in my care with REVLIMID® (lenalidomide).

Date:	01-May-2007	No		

Patient Name: DOE, JANE
Address: 1 MAIN STREET, SUMMIT, NJ 07901
Telephone Number: 111-111-1111
Social Security No: 123-45-7890
Date of Birth: 01-Jan-1999
Sex: F
ICD-9 Diagnosis Code: 238.7 MDS: MYELODYSPLASTIC SYNDROMES

Parent/Guardian Signature: _____
Date: _____

I have fully explained to the parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females of childbearing potential. I have asked the parent/guardian if he/she has any questions regarding the child's treatment with REVLIMID® (lenalidomide) and have answered those questions to the best of my ability. I will comply with all of my obligations and responsibilities as a prescriber registered under RevAssist®.

Prescriber Name: DOE, MARK
DEA Number: AD1234567
Social Security No: --
Address: 11 MAIN ST, SUMMIT, NJ 07901
Telephone Number: 111-111-1234
Fax Number: 111-111-1111

Prescriber Signature: _____
Date: _____

FAX THIS FORM TO 1-888-432-9325

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Female Child of Childbearing Potential

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

Special Prescribing Requirements

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID® (lenalidomide), REVLIMID® (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED "REVASSIST®". UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID® (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE REVASSIST® PROGRAM.

2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

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You can get information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll-free number at 1-888-423-5436.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Female Child of Childbearing Potential

For more information please see the REVLIMID® Medication Guide.

Patient/Guardian: Please read thoroughly and initial inside of the box provided, if you agree with the statement. Please keep a copy of this Patient-Physician Agreement Form for your records.

Initial

1. I understand that the child in my care must not take REVLIMID® (lenalidomide) if she is pregnant, breast-feeding a baby, or able to get pregnant and not using the required two methods of birth control. ☐

2. I understand that birth defects may occur with the use of REVLIMID® (lenalidomide). I have been warned by our doctor that an unborn baby may have birth defects or may even die if the child in my care is pregnant or becomes pregnant while taking REVLIMID® (lenalidomide). ☐

3. I understand that if the child in my care is able to become pregnant, she must use at least one highly effective method and one additional effective method of birth control (contraception) AT THE SAME TIME: ☐

At least one highly effective method	**AND**	**One additional effective method**
IUD		Latex condom
Hormonal (birth control, pills, injections, patch, implants)		Diaphragm
Tubal ligation (tubes tied)		Cervical cap
Partner's vasectomy		

These birth control methods must be used for at least 4 weeks before starting REVLIMID® (lenalidomide) therapy, all during REVLIMID® (lenalidomide) therapy, during therapy interruption, and for at least 4 weeks after REVLIMID® (lenalidomide) therapy has stopped. She must use these methods unless she completely abstains from heterosexual sexual contact. If a hormonal (birth control pills, injections, patch, or implants) or IUD method is not medically possible for her, she may use another highly effective method or two barrier methods AT THE SAME TIME.

4. I know that the child in my care must have a pregnancy test done by our doctor within the 10 to 14 days and 24 hours prior to being prescribed REVLIMID® (lenalidomide), even if my child's menses has stopped due to treatment for my child's disease, then every week during the first 4 weeks of REVLIMID® (lenalidomide) therapy. She will then have a pregnancy test every 4 weeks if she has regular and/or no menstrual cycles, or every 2 weeks if her cycles are irregular while she is taking REVLIMID® (lenalidomide). ☐

5. I know that the child in my care must immediately stop taking REVLIMID® (lenalidomide) and that I must inform our doctor if she becomes pregnant while taking the drug, if she misses her menstrual period, or experiences unusual mentrual bleeding, stops using birth control, or thinks, FOR ANY REASON, that she may be pregnant. If our doctor is not available, I can call 1-888-668-2528 for information on emergency contraception. ☐

AD1234567-7890

6. The child in my care is not now pregnant, nor will she try to become pregnant for at least 4 weeks after she has completely finished taking REVLIMID® (lenalidomide). ☐

7. I understand that REVLIMID® (lenalidomide) will be prescribed ONLY for the child in my care. She must not share it with ANYONE, even someone who has similar symptoms to her. It must be kept out of the reach of children and should NEVER be given to females who are able to have children. ☐

8. I agree any unused drug will be returned to Celgene by calling 1-888-423-5436. Shipping costs will be paid by Celgene. I understand that Celgene cannot provide patients with a refund for the unused drug. ☐

9. I have read the REVLIMID® (lenalidomide) patient brochure. I understand the contents, including other possible health problems or "side effects" from REVLIMID® (lenalidomide). I know that she cannot donate blood while taking REVLIMID® (lenalidomide) or for 4 weeks after stopping REVLIMID® (lenalidomide). ☐

10. I understand that we must participate in a telephone survey and patient registry while she is on REVLIMID® (lenalidomide). ☐

11. Our doctor has answered any questions that we have asked. ☐

12. I understand that we might be asked to participate in an additional voluntary survey by mail or telephone to evaluate the RevAssist® program. Our agreement or disagreement will not interfere with my child's ability to receive REVLIMID® (lenalidomide). ☐

13. I acknowledge that we may be contacted by a Celgene representative in regards to my child following the rules with the RevAssist® program. ☐

REVLIMID® Patient-Physician Agreement Form

Female Child of Childbearing Potential

Authorization:
I understand that by signing this Authorization, I permit my healthcare providers and pharmacies to disclose to Celgene Corporation, its agents and contractors, my medical and other health information for the following purposes:

(a) coordinate the delivery of products and services available through pharmacies and Celgene's patient assistance programs;
(b) conduct data analyses regarding the use of REVLIMID® (lenalidomide);
(c) comply with applicable law;
(d) provide me with information regarding REVLIMID® (lenalidomide).

I understand that I may be contacted by Celgene or its agents and asked if I am willing to voluntarily answer additional survey questions that will help to evaluate RevAssist®.

This Authorization will be effective for 12 months after the date on which I stop receiving REVLIMID® (lenalidomide). However it may be revoked earlier, at any time, by me informing my healthcare provider that I will no longer participate in RevAssist®.

I understand that once my information is disclosed, there is no guarantee that the recipient of the information will not re-disclose it, and the recipient may not be required to abide by this Authorization.

I understand that I may refuse to sign this Authorization. Such refusal constitutes a refusal to participate in RevAssist®, and will affect my ability to receive REVLIMID® (lenalidomide).

I understand that I may refuse to participate in the voluntary survey. My refusal to participate in the survey will not change how my healthcare providers and pharmacies provide my medical treatment, and will not affect my ability to receive REVLIMID® (lenalidomide).

Yes_____ No_____ I authorize the information disclosure as described above.

Yes_____ No_____ I agree to participate in the voluntary survey described above.

UPON SIGNING THIS AUTHORIZATION, PATIENT HAS THE RIGHT TO OBTAIN A COPY, UPON REQUEST.

AD1234567-7890

REVLIMID® Patient-Physician Agreement Form

Female Child of Childbearing Potential

This information has been read aloud to us in the language of our choice. I understand that if we do not follow all of our doctor's instructions, the child in my care will not be able to receive REVLIMID® (lenalidomide). I also understand that the information we provide on this Patient-Physician Agreement Form and as part of ongoing surveys will be known by the manufacturer of REVLIMID® (lenalidomide) and the FDA. However, the information will not be used for commercial purposes.

The below party now authorizes my child's doctor to begin treating the child in my care with REVLIMID® (lenalidomide).

Date:	01-May-2007	Yes		

Patient Name: DOE, JANE
Address: 1 MAIN STREET, SUMMIT, NJ 07901
Telephone Number: 111-111-1111
Social Security No: 123-45-7890
Date of Birth: 01-Jan-1990
Sex: F
ICD-9 Diagnosis Code: 238.7 MDS: MYELODYSPLASTIC SYNDROMES

Parent/Guardian Signature: _____
Date: _____

I have fully explained to the parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females of childbearing potential. I have asked the parent/guardian if he/she has any questions regarding the child's treatment with REVLIMID® (lenalidomide) and have answered those questions to the best of my ability. I will comply with all of my obligations and responsibilities as a prescriber registered under RevAssist®.

Prescriber Name: DOE, MARK
DEA Number: AD1234567
Social Security No: --
Address: 11 MAIN ST, SUMMIT, NJ 07901
Telephone Number: 111-111-1234
Fax Number: 111-111-1111

Prescriber Signature: _____
Date: _____

FAX THIS FORM TO 1-888-432-9325

AD1234567-7890

REVLIMID® *(lenalidomide)* *Patient Prescription Form*

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

Patient Last Name _____ Patient First Name _____

Home Phone Number (____)_____

Other Phone Number (____)_____ Ext. _____

Home Address _____

City _____ State _____ ZIP _____

Shipping Address (If different from home address) _____

_____

Date of Birth _____ SS#/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_____

DEA Number_____

Prescriber Phone Number (____)_____ Ext. _____

Fax Number (____)_____

Prescriber Address _____

_____

City _____ State _____ ZIP _____

Office Contact Name _____

Office Contact Phone Number _____

Patient Type From PPAF (Check one)

❑ Adult Female—NOT of Childbearing Potential

❑ Adult Female—Childbearing Potential

❑ Adult Male

❑ Female Child—NOT of Childbearing Potential

❑ Female Child—Childbearing 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 # _____

I consent to have my medical information shared with the Patient Support Coordinator® (PSC®) for reimbursement purposes. My consent is valid for a period no longer than 12 months from today's date and can be revoked at any time by contacting PSC® at 1-800-931-8691.

Patient Signature _____

Date _____

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

REVLIMID®

Dose	Quantity	Directions
❑ **5 mg**	_____	_____
❑ **10 mg**	_____	_____
❑ **15 mg**	_____	_____
❑ **25 mg**	_____	_____

Recommended Starting Dose: See below for dosage

❑ **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)

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

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

IMPORTANT INFORMATION ABOUT RevAssist®

- To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called "RevAssist®"
- Only prescribers registered with RevAssist® can prescribe REVLIMID® (lenalidomide)
- Only RevAssist® contract pharmacies can dispense REVLIMID® (lenalidomide)
- In order to receive REVLIMID® (lenalidomide), patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program
- Information about REVLIMID® (lenalidomide) and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com

How to Fill a REVLIMID® (lenalidomide) Prescription

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

2. HCP completes survey

3. HCP completes patient prescription form

4. HCP obtains RevAssist® authorization number

5. HCP provides authorization number on patient prescription form and patient signs, indicating consent to share medical information with PSC® for reimbursement support, if necessary

6. **HCP faxes form, including prescription, to one of the RevAssist® contract pharmacies (see below)**

7. HCP advises patient that a representative from a RevAssist® contract pharmacy will contact them

8. RevAssist® contract pharmacy conducts patient education

9. RevAssist® contract pharmacy calls for confirmation number

10. RevAssist® contract pharmacy ships REVLIMID® to patient with the FDA-approved MEDICATION GUIDE

RevAssist® Pharmacy Network

The RevAssist® Pharmacy Network is the list of contract pharmacies to be faxed the Patient Prescription Form

Accredo-Medco Specialty REVLIMID® Team
Phone: 1-800-601-7149
Fax: 1-800-590-1021

Advanced Care Scripts
Phone: 1-866-681-7131
Fax: 1-866-679-7131

Aetna Specialty Pharmacy
Phone: 1-866-782-2779
Fax: 1-866-329-2779

Axium Healthcare Pharmacy, Inc.
Phone: 1-888-315-3395
Fax: 1-888-315-3270

Biologics Inc.
Phone: 1-800-850-4306 (toll-free)
or 1-919-546-9810 (direct)
Fax: 1-919-546-9816

BioScrip® Pharmacy
Phone: 1-877-842-5097
Fax: 1-866-368-9810

Care Advantage Pharmacy
Phone: 1-817-837-8601
Fax: 1-817-837-8686

Caremark Connect
Phone: 1-800-237-2767
Fax: 1-800-323-2445

CuraScript Pharmacy
Phone: 1-866-883-2568
Fax: 1-866-883-2572

Diplomat Specialty Pharmacy
Phone: 1-877-977-9118
Fax: 1-800-550-6272

ivpcare/OTN Specialty
Phone: 1-800-424-9002
Fax: 1-800-874-9179

McKesson Specialty
Phone: 1-888-456-7274
Fax: 1-888-591-8482

Medfusion Rx Pharmacy
Phone: 1-888-432-2797
Fax: 1-888-229-8897

Medmark A Walgreens Specialty Pharmacy
Phone: 1-877-231-8302
Fax: 1-888-347-3416

PharmaCare Specialty Pharmacy
Phone: 1-800-854-4299
Fax: 1-800-862-1249

PrecisionRx Specialty Solutions
Phone: 1-866-468-5787
Fax: 1-866-389-5210

Specialty Scripts Pharmacy
Phone: 1-800-218-5688
Fax: 1-800-830-5292

US Bioservices
Phone: 1-888-518-7246
Fax: 1-888-418-7246

Walgreens Specialty Pharmacy
Phone: 1-866-202-4014
Fax: 1-877-777-9402

RevAssist® program for REVLIMID® education and prescribing safety

RevAssist®

Guidelines for Ordering, Counseling, and Dispensing REVLIMID® (lenalidomide)

IMPORTANT INFORMATION ABOUT RevAssist®

- To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called "RevAssist®"
- Only prescribers registered with RevAssist® can prescribe REVLIMID® (lenalidomide)
- Only RevAssist® contract pharmacies can dispense REVLIMID® (lenalidomide)
- In order to receive REVLIMID® (lenalidomide), patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program
- Information about REVLIMID® (lenalidomide) and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.REVLIMID.com

Dear Pharmacist:

Please see below the required procedures for the RevAssist® program.

- Dispensing pharmacists must be educated on the RevAssist® program and on dispensing procedures for REVLIMID® capsules
- Only accept prescriptions with an authorization number. Authorization numbers and prescriptions are valid for 7 days for females of childbearing potential and 14 days for all other patients. Telephone prescriptions are not permitted
- Call each unique authorization number on every prescription into the automated system at the Celgene Customer Care Center, open 24 hours a day, 7 days a week, at 1-888-423-5436
  - Enter NABP number or DEA number
  - Enter authorization number written on prescription
  - Enter number of capsules and milligram (mg) strength being dispensed
- If you do not obtain a confirmation number, do not dispense REVLIMID®. Contact the patient's physician and Celgene for further instruction
- Write the confirmation number on the prescription. This confirmation number is only valid for 24 hours
- Provide patient counseling per the RevAssist® program requirements
- Dispense no more than a 4-week (28-day) supply with the FDA-approved MEDICATION GUIDE. A new prescription is required for further dispensing
- **DISPENSE SUBSEQUENT PRESCRIPTIONS ONLY IF FEWER THAN 7 DAYS OF THERAPY REMAIN ON THE PREVIOUS PRESCRIPTION**

If you have any questions, please call the Celgene Customer Care Center at **1-888-423-5436**.

Revlimid® (lenalidomide) capsules

Reference ID: 3128570

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

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

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

Special Prescribing Requirements

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID® (lenalidomide), REVLIMID® (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED "REVASSIST®". UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID® (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE REVASSIST® PROGRAM.

2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID® (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY PRESCRIBED IN CONJUNCTION WITH REVLIMID® (lenalidomide) MAY LESSEN THE POTENTIAL FOR VENOUS THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT'S UNDERLYING RISK FACTORS.

You can get the information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at www.REVLIMID.com or by calling the manufacturer's toll free number 1-888-423-5436.

IMPORTANT SAFETY INFORMATION

Hypersensitivity: REVLIMID® (lenalidomide) is contraindicated in any patients who have demonstrated hypersensitivity to the drug or its components.

Renal impairment: REVLIMID® (lenalidomide) is substantially excreted by the kidney, so the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it would be prudent to monitor renal function.

Nursing mothers: It is not known whether REVLIMID® (lenalidomide) is excreted in human milk. Because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

Other most common adverse events: Multiple Myeloma (REVLIMID®/dexamethasone): constipation (39%), fatigue (38%), insomnia (32%), muscle cramp (30%), diarrhea (29%), neutropenia (28%), anemia (24%), asthenia (23%), pyrexia (23%), nausea (22%), headache (21%), peripheral edema (21%), dizziness (21%), dyspnea (20%), tremor (20%), decreased weight (18%), thrombocytopenia (17%), rash (16%), back pain (15%), hyperglycemia (15%), and muscle weakness (15%). **del 5q MDS (REVLIMID®):** diarrhea (49%), pruritus (42%), rash (36%), fatigue (31%), constipation (24%), nausea (24%), nasopharyngitis (23%), arthralgia (22%), pyrexia (21%), back pain (21%), peripheral edema (20%), cough (20%), dizziness (20%), headache (20%), muscle cramp (18%), dyspnea (17%), and pharyngitis (16%).

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

Revlimid® (lenalidomide) capsules

RevAssist® program for REVLIMID® (lenalidomide) education and prescribing safety

Education and Counseling Checklist for Pharmacies

Authorization #_____ Confirmation #_____ Date_____

Pharmacy Name _____ Counselor Name _____

Work Phone #_____ Extension _____ Pharmacy Address _____

City _____ State _____ ZIP Code_____

Patient Name _____ Date of Birth _____ SS #_____

Checklist for females of childbearing potential

I counseled adults and children on:

- ❑ Potential fetal harm
- ❑ Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse
- ❑ Continuation of 2 forms of birth control if therapy is interrupted and for 4 weeks after therapy is discontinued
- ❑ Obtain a pregnancy test 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
- ❑ The need to stop taking REVLIMID® right away in the event of becoming pregnant and to call their healthcare provider immediately. Female partners of males taking REVLIMID® must call their healthcare provider right away if they get pregnant
- ❑ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- ❑ Reminder 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 medication
- ❑ Not donating blood while taking REVLIMID® and for 4 weeks after stopping REVLIMID®
- ❑ Not to break, chew, or open REVLIMID® capsules
- ❑ Instructions on REVLIMID® dose and administration Dose _____ # of Capsules Dispensed _____

Female children (<18 years of age):

- ❑ Parent or legal guardian must have read the RevAssist® education material and agreed to ensure compliance

Checklist for females NOT of childbearing potential (natural menopause for at least 24 consecutive months, a hysterectomy, or bilateral oophorectomy)

I counseled adults and children on:

- ❑ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- ❑ Reminder 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 medication
- ❑ Not donating blood while taking REVLIMID® and for 4 weeks after stopping REVLIMID®
- ❑ Not to break, chew, or open REVLIMID® capsules
- ❑ Instructions on REVLIMID® dose and administration Dose _____ # of Capsules Dispensed _____

Female children (<18 years of age):

- ❑ Parent or legal guardian must have read the RevAssist® education material and agreed to ensure compliance
- ❑ Must inform their physician when they begin menses

Checklist for males

I counseled adults and children on:

❑ Potential fetal harm and contraception (wearing a latex condom when engaging in sexual intercourse with a female of childbearing potential)

❑ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism

❑ Reminder 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 medication

❑ Not donating blood or sperm while taking REVLIMID® and for 4 weeks after stopping REVLIMID®

❑ Not to break, chew, or open REVLIMID® capsules

❑ Instructions on REVLIMID® dose and administration Dose _____ # of Capsules Dispensed _____

Male children (<18 years of age):

❑ Parent or legal guardian must have read the RevAssist® education material and agreed to ensure compliance

DO NOT dispense or ship REVLIMID® (lenalidomide) to a patient unless all the following are done:

- Prescription has an authorization number
- You have counseled the patient
- You have obtained a confirmation number
- You are shipping the product within 24 hours of obtaining the confirmation number
- The FDA-approved MEDICATION GUIDE is included with the prescription
- You confirm the prescription is no more than a 28-day supply and there are 7 days or less remaining on an existing REVLIMID® prescription

All boxes and spaces must be marked or filled in during counseling with patient for every prescription.
Ensure there are no blank spaces or boxes before signing.

Counselor Signature: _____ **Date:** _____

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

04/08 REV08023

Healthcare Professional Adverse Drug Experience Reporting Procedure

Celgene is committed to ensuring patient safety through the monitoring of Adverse Drug Experiences associated with the use of REVLIMID®.

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: 908-673-9667
- Toll Free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Customer Care Center)
- Fax: 908-673-9115
- Mail: Global Drug Safety & Risk Management, Celgene Corporation, 86 Morris Avenue, Summit, NJ 07901

Reporting to FDA:

Adverse drug experiences that are suspected to be associated with the use of REVLIMID® and any suspected pregnancy 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

REVLIMID® lenalidomide) Pregnancy Exposure Registry

Version 1.

Celgene Corporation
863Morris Ave.
Summit,3NJ307901

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1. INTRODUCTION

The goal of the program is to minimize the risk of fetal exposure to REVLIMID® lenalidomide) due to the potential of fetal harm. 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 embryofetal 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. RevAssist® Program

Because of the potential teratogenic effects of REVLIMID and to avoid fetal exposure, REVLIMID is available only under a special restricted distribution program called "RevAssist" for REVLIMID education and prescribing safety. Under this program, only prescribers and contracted pharmacists registered with the program are able to prescribe and dispense the product. In addition, REVLIMID must be dispensed only to patients who are registered and meet all the conditions of the RevAssist program. Contracted 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 FDA-approved 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 fetal exposure. Patients may also enter into a voluntary survey that is administered through Covance. The voluntary survey is designed to assess patient understanding of key safety message of the RevAssist program.

In the RevAssist program, a female patient of childbearing potential (FPCBP) 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). Registered FPCBP need to complete a brief, confidential survey monthly before a prescription can be written for the medication. A RevAssist contract pharmacy will contact the patient by phone to discuss REVLIMID therapy. The patient will not receive the medication unless she speaks with the RevAssist contract pharmacy. The FPCBP 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 FPCBP 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 50mIU/mL. A pregnancy test is to be performed weekly during the first 4 weeks, and then repeated every 4 weeks among FPCBP with regular menstrual cycles. If menstrual cycles are irregular, testing should occur

every 2 weeks. In the event of pregnancy, the FPCBP 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-10883 and to Celgene at 1-888-423-5436.

1.2. Full Prescribing Informationu

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 fetal exposure to REVLIMID should be reported to the FDA via the MedWatch number at 1-800-FDA-10883 and also to Celgene Corporation at 1-888-423-5436.

The FDA-approved 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-10883 and to Celgene Corporation at 1-888-423-5436.

2. OBJECTIVE

Celgene is committed to investigating any reports of possible 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 childbearing 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 RevAssist® program in the United States, Celgene Pregnancy Prevention Plan programs in the rest of the world (ROW), voluntary survey from Covance Inc., 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 United States Risk Management System US RMS) 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 of3Pregnant Partner will be utilized for the root cause analysis of3pregnancy. The letters and the forms are found in Appendix 1 and the definition of3terms is found in Appendix 2.

The processes are presented in Figure 1, Figure 23and Figure .

3.1. Pregnancy/Pregnancy Background

3.1.1. Health Care Providers

- When a pregnancy is reported,3the Drug Safety Specialist (DSS) or designee will make an outbound call to the reporter to verify the pregnancy. If3there is no response,3 the DSS3or designee will make another outbound call to the reporter to verify the pregnancy.
- If3the pregnancy is verified,3the DSS3will generate a letter and a Pregnancy Background Form that will be sent to the health3care provider (HCP;3prescriber,3 clinical investigator,3obstetrician,3primary care physician).
- If3no response is received within 303days,3the letter and Pregnancy Background Form will be resent.
- If3there is no response to the second letter within 303days,3an outbound call will be made to the HCP (prescriber,3clinical investigator,3obstetrician,3primary care physician) requesting that the Pregnancy Background Form be completed.
- If3there is no response to the outbound call from the obstetrician/primary care physician within 303days,3all contacts and attempts will be documented in the case.
- If3there is no response to the outbound call from the clinical investigator,3the clinical study manager will be contacted to assist in obtaining the response from the clinical investigator.
- If3there is no response to the outbound call from the prescriber within 303days, he or she will be flagged. When the flagged prescriber request for a prescription authorization,3the call will be directed to the DSS3or designee who will remind the prescriber to complete the Pregnancy Background Form.
- If3there is no response within 303days,3the DSS3or designee will document all contacts and attempts. If3the completed Pregnancy Background Form is received,3the DSS3or designee will unflag the Prescriber.
- The DSS3or designee will process the completed Pregnancy Background Form.

3.1.2. Patient and Male Patient of Pregnant Partner

- A3letter and a Pregnancy Background Form for patient and male patient of3pregnant partner will be sent when appropriate) within 303days after a report of3confirmed pregnancy to patients registered in the RevAssist® program. The letter and the form for patient and male patient of3pregnant partner will be sent to the clinical investigator for completion of3the study subject at the next study visit. The Pregnancy Background Form will collect information for the root cause analysis of3pregnancy.

- 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 registered in the RevAssist 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 O tcome

3.3.1. Health Care Providers

- For confirmed pregnancies, a 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 prescri ber, 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-upu

- 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 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-3 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, 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 patient of childbearing potential (FPCBP) will be determined by dividing the total number of FPCBP experiencing at least one pregnancy over the total FPCBP 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 RevAssist® 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 243hours of3receipt 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,3lenalidomide,3thalidomide) or a requirement in the clinical study protocol for immediate notification,3all Celgene personnel,3including affiliates and licensed partners,3shall inform Global Drug Safety or the appropriate Celgene Drug Safety department worldwide **IMMEDIATELY** by a telephone call followed by electronic transmission (email or facsimile) of3a serious adverse event report of3any possible exposure of3a 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:3

- Number of3pregnancies in patients and partners of3patients with3outcome known stratified by live birth,3spontaneous abortions,3elective terminations, fetal deaths/stillbirths)
- Number of3pregnancies with3outcome pending
- Number of3pregnancies lost to follow-up
- Pregnancy proportions for FPCBP patients and for male patients,3stratified by prescribing environment
- Number of females of3childbearing potential exposed for postmarketing and clinical trials (US3and ROW*) during the time period
- Number of3males exposed for postmarketing and clinical trials (US3and ROW*) during the time period

*Note:3RevAssist® is unique to the United States. In other countries where REVLIMID is marketed,3such3controlled distribution may not be possible because of3legal restraints. Hence,3accurate data on patient demographics will not be available.

For pregnancies with known outcome,3the status report will include line listings and summaries of:3

- Demographics,3obstetrical and medical history of3mothers
- Weeks of3gestational age at exposure
- Type,3dose and duration of3exposure
- Weeks of3gestational age at completion or termination of3pregnancy
- For live births and deaths/stillbirths,3whether multiple birth,3small for gestational age,3 pre-term delivery and congenital anomalies or other fetal abnormalities
- For spontaneous abortions and elective terminations,3abnormalities in products of3 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,31993:A32-A100,3 77) 488-7160.

EMEA Committee for Medicinal Products for Human Use:3*Guideline on the Exposure to Medicinal Products During Pregnancy: Need for Post-Authorisati n Data.* London,3UK. 14Nov2005.

Food and Drug Administration. *Guidance for Industry Establishing Pregnancy Exposure egistries.* Rockville,3Md. August 2002.

Investigator's Brochure for Lenalidomide ver 9. Summit,3NJ:Celgene Corporation, 8Mar2006.

REVLIMID® [Full Prescribing Information and the FDA-approved Medication Guide]. Summit,3 NJ:3Celgene Corporation;32005.

RevAssist® Program for REVLIMID® education and prescribing safety.

Fig re 1:u Pregnancy Background and Follow -Up Process Flow -HuP

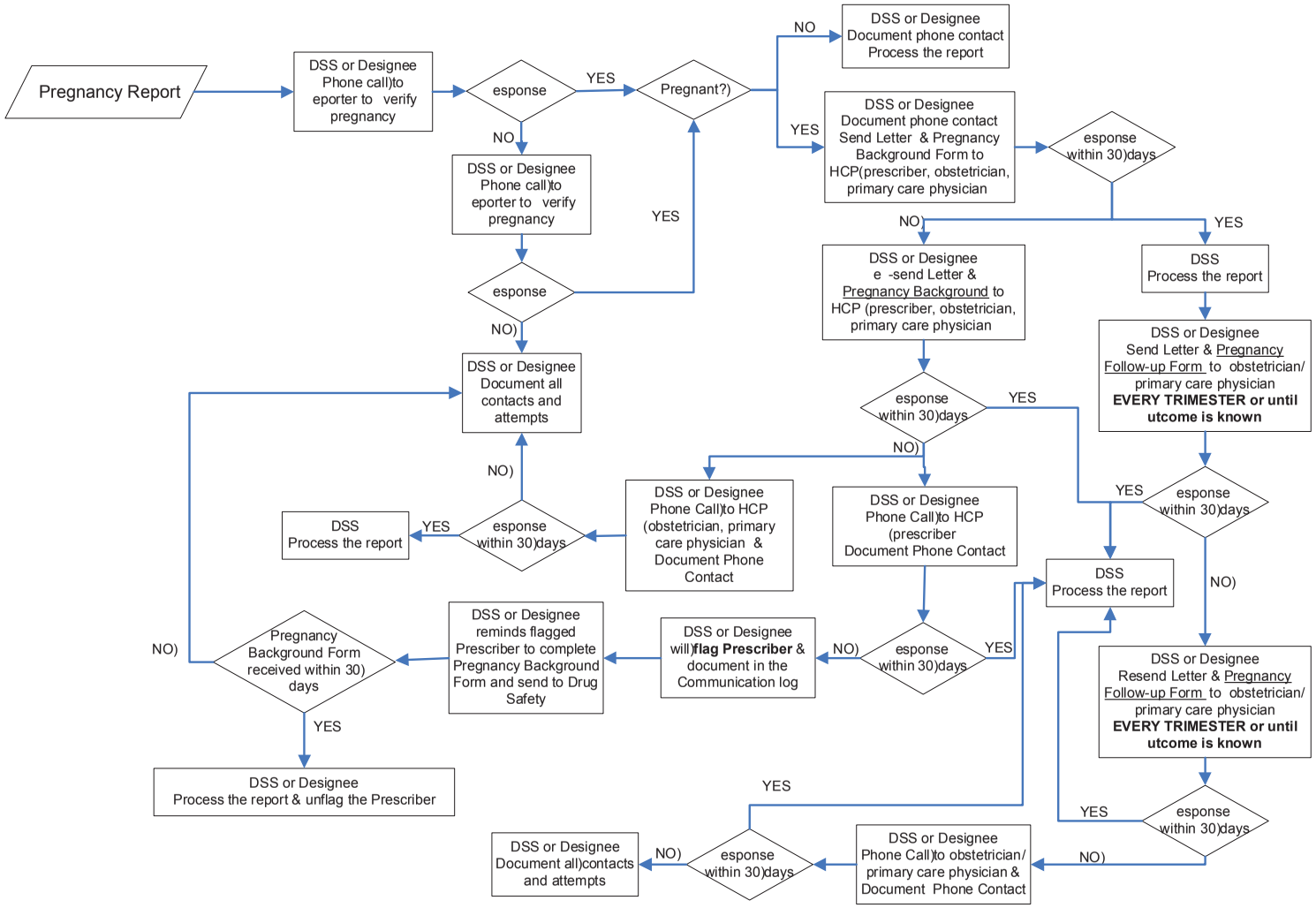


Fig re 2:u Pregnancy O tcome and Infant Follow -Up Process Flow -HuPN

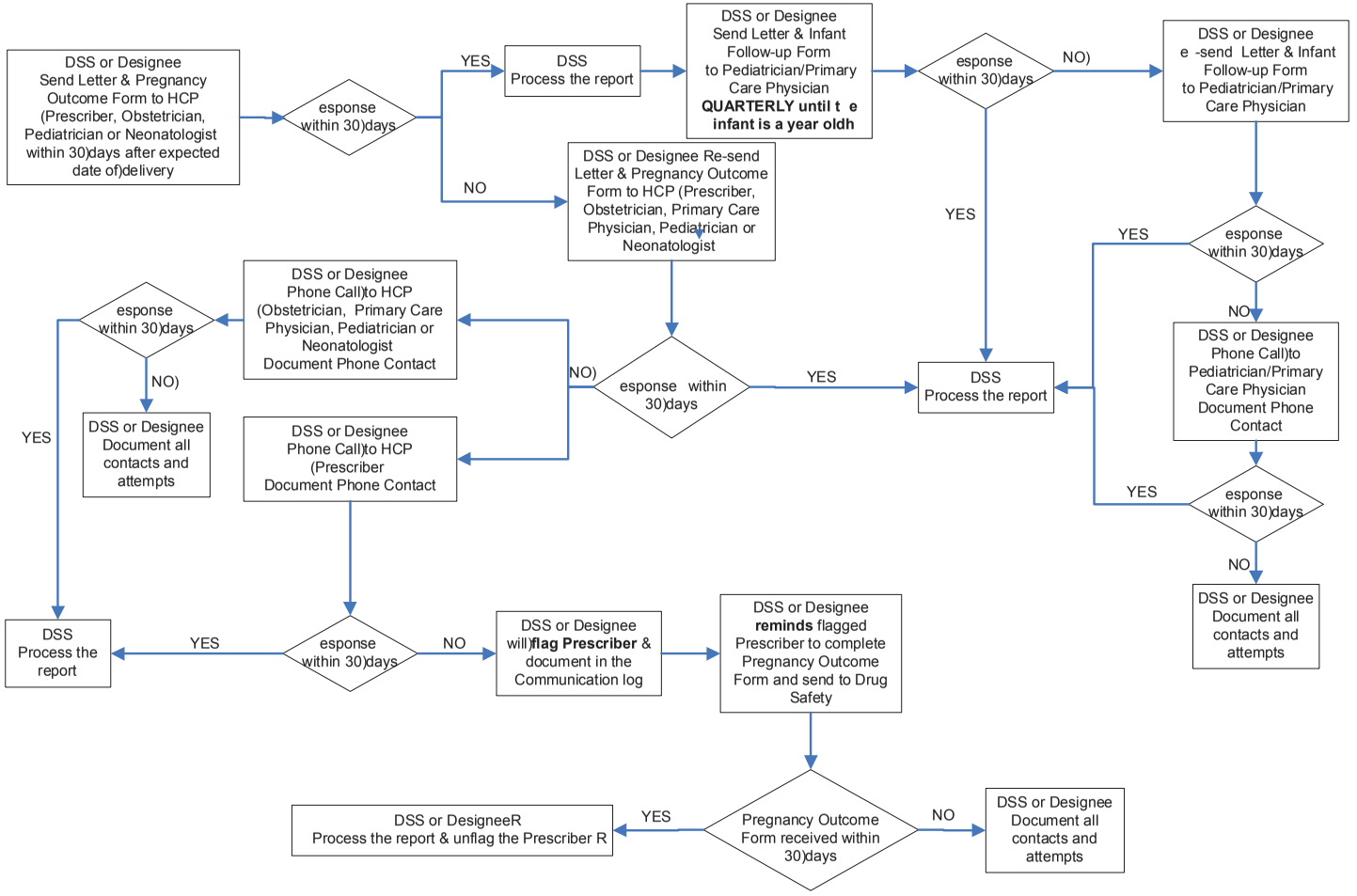
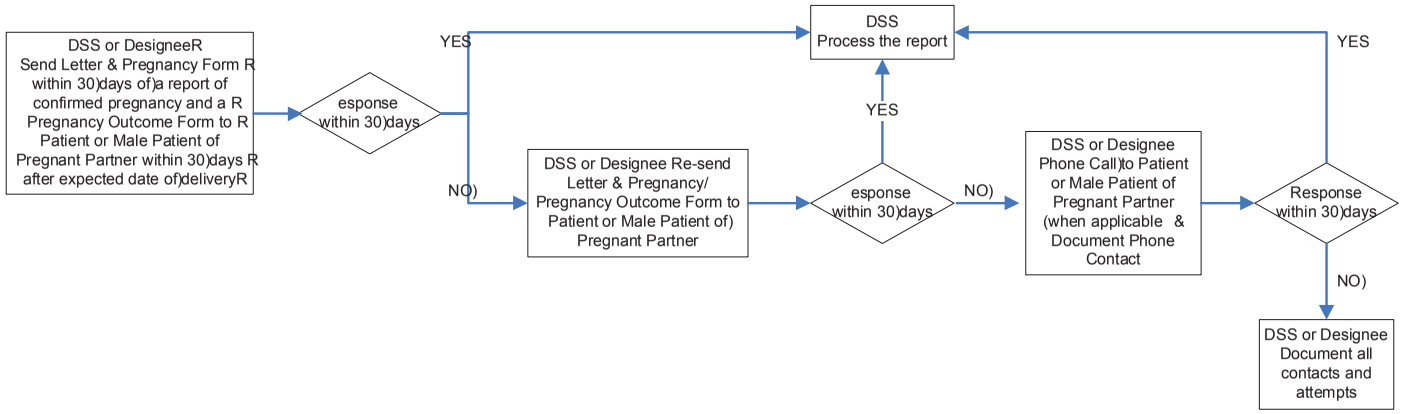


Fig re 3:u Pregnancy/Pregnancy O tcome Process Flow -Patient and Male Patient of Pregnant PartnerN



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 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 of3Patient
Address:3

DDMMYYYY3

Re: Patient Identifier: [patient identifier]3
Patient DOB,3Patient sex
Drug: [Primary Suspect Product Name]3
Our Manufacturer Control No (MCN): [MCN]3

Dear [Patient's Name]3

The Celgene Corporation Global Drug Safety Department has received a report of3your [your partner's pregnancy].

Celgene is committed to investigating any reports of3possible fetal exposure to our products whether it be the patient or patient's partner. In order to perform a thorough3evaluation and to meet our regulatory reporting requirements throughout the world, we are interested in obtaining additional details regarding your [your partner's]3pregnancy. Please be assured that all information will be treated in the strictest of3confidence.

Please complete the enclosed Event-Specific Questionnaire for Patient or Male Patient of3Pregnant Partner –3Pregnancy Background/3Event-Specific Questionnaire for Patient or Male Patient of3Pregnant Partner –3Pregnancy Outcome Form and return to Celgene Drug Safety via mail (self-addressed envelope provided),3or FAX3to (908) 673-9115.

If3you have any questions,3please do not hesitate to contact me at 1-800-640-7854.

Thank3you in advance for your assistance.

Name of Specialist
Title

Event-Specific Questionnaire for HuP – Pregnancy Background
(Patient or Partner of Patient)
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Dr gsafety@celgene.comN

Repnrter Information					
EPO) TE) NAME:)					
ADDRESS:)		CITY, STATE, ZIP, COUNT) Y:)			
PHONE)NO.:)		FAX)NO.:)			
Obstetrician Information (Please provide)h					
OBSTET) ICIAN)NAME:)					
ADDRESS:)		CITY, STATE, ZIP, COUNT) Y:)			
PHONE)NO.:)		FAX)NO.:)			
Patient Information					
PATIENT)ID:)	DATE)OF BI) TH:)	ETHNICITY:) ☐WHITE) ☐AFRICAN-AME) ICAN) ☐ASIAN) ☐ OTHE) , SPECIFY:)			
Partner of Patient Information ☐ Not applicable					
DATE)OF BI) TH:)	ETHNICITY:) ☐ WHITE) ☐ AFRICAN-AME) ICAN) ☐ ASIAN) ☐ OTHE) , SPECIFY:)				
Patient Treatment Information: REVLIMID®h					
LOT)NO.)	EXPI) Y)DATE:)	DOSE:)	F EQUENCY:)	OUTE:)	
STA) T)DATE)		STOP DATE)			
INDICATION)FO) USE)					
CYTOGENETIC ABNO) MALITIES:) ☐NO)☐YES, IF YES, SPECIFY:)					
Current Pregnancyh					
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 Historyh		
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 Historyh

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 Historyh

	DATE OF DIAGNOSIS		*DATE OF DIAGNOSIS*
CANCE) ☐ NO ☐ YES, IF YES, SPECIFY) _____h			

cial Historyh

ALCOHOL ☐ NO) ☐ YES, IF YES, AMOUNT/UNIT)CONSUMED PE) D AY:)

TOBACCO) ☐ NO) ☐ YES	IV)O) ECREATIONAL DRUG)USE) ☐ NO) ☐ YES, SPECIFY)

Family History: CONGENITAL ABNO) MALITIES ☐ NO) ☐ YES, SPECIFY:)

Medications/Treatments (including erbal, alternative and over t e counter medicines and dietary supplements) During Pregnancy

DRUG	*STAR DATE*	*S OP DATE/ CONTINUING*	*INDICATION*

Adverse Event(s) During Pregnancyh

Event(s	SE) IOUS		SE) IOUS C ITE) IA)[1)]	STA) T) DATE)	STOP DATE)	CAUSAL ELATIONSHIP TO)CELGENE) P ODUCT)		
	N) O)	Y) E) S				YES	NO)	If)No, what medications, disease states etc played a role in the event.)

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

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

MCN:h

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

Date _____3
Name of3Patient or Name of Male Patient of3Partner _____3

For a better understanding of3pregnancy among patients or partners of3patients on Revlimid® and for further improvement of3he RevAssist® program,3please complete the following questions.

1. What forms of birth3control have you been using while on Revlimid before you/your partner got pregnant?3Please check3all that applies.

□3IUD
□ Hormonal birth3control pills, hormonal patches,3injections,3implants)
□ Tubal ligation
□3Partner's vasectomy
□3Latex condom
□3Diaphragm
□ Cervical cap or shield
□ Spermicide or sponge
□ Withdrawal

2. Were you or your partner at any time during use of3Revlimid without contraception for even one day?3

□ No,3please proceed to Q53
□ Yes,3please answer Q3, Q4, Q5,3and Q63

. How3often did you have unprotected sexual intercourse?3

□3multiple times
□3once a week3
□3once every 2 weeks
□3once a month3
□3not at all
□3other,3specify _____3

4. Why did you or your partner interrupt or stop using contraception?3

☐ wanted a child

☐3partner disapproved

☐3side effects

☐ health3concerns

☐3nconvenient to use

☐3other,3specify _____3

5. Did you receive the Revlimid Medication Guide?3

☐ No,3please proceed to Q63

☐ Yes,3please answer the following question

5.1 Did you read the Revlimid Medication Guide?

☐ No,3please proceed to Q6

☐ Yes,3please answer the following question(

5.2 Did you understand the information in the Revlimid Medication Guide?3

☐ No

☐ Yes

6. Where did most of3your knowledge about contraception during Revlimid® use come from?3

☐3physician who prescribed Revlimid

☐3RevAssist® Information booklet

☐3Revlimid Medication Guide

☐ Other,3specify _____3

7. Do you feel you and/or your partner had good understanding of3the risk3of3pregnancy during Revlimid use?3

☐ Yes

☐ No

☐3Don't know3

Event-Specific Questionnaire for HuP – Pregnancy Follow-up N
(Patient or Partner of Patient)
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Dr gsafety@celgene.comN

Date:h	**Period Chvered: [Date] to [Date]h**
Repirter Information	
EPO) TE) NAME:)	
ADDRESS:)	CITY, STATE, ZIP, COUNT) Y:)
PHONE)NO.:)	FAX)NO.:)
Name of Patient or Pregnant Partner of Male Patient	
Current Pregnancyh	
Prenatal)Tests	

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

Medications/Treatments (including erbal, alternative and over t e counter medicines and dietary supplements) During Pregnancy

DRUG	*S ART DATE*	*S OP DATE/ CONTINUING*	*INDICATION*

Adverse Event(s) During Pregnancyh

Event(s	SE) IOUS		SE) IOUS C ITE) IA)[1)]	STA) T) DATE)	STOP DATE)	CAUSAL ELATIONSHIP TO)CELGENE) P ODUCT)		
	N) O)	Y) E) S				YES	NO)	If)No, what medications, disease states etc played a role in the event.)

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

IGNATURE OF PERSON COMPLETING THIS FORM ..... DATE .....

MCN:h

Event-Specific Questionnaire for HuP – Pregnancy O tcome N
(Patient or Partner of Patient)
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Dr gsafety@celgene.comN

Repht er Information					
EPO) TE) NAME:)					
ADDRESS:)				CITY, STATE, ZIP, COUNT) Y:)	
PHONE)NO.:)				FAX)NO.:)	
Patient Information					
PATIENT)ID:)	DATE)OF BI) TH:)	ETHNICITY:) ☐WHITE) ☐AFRICAN-AME) ICAN) ☐OTHE) , SPECIFY:)			
Partner of Patient Information ☐ Not applicable					
DATE)OF BI) TH:)		ETHNICITY:) ☐WHITE) ☐AFRICAN-AME) ICAN) ☐OTHE) , SPECIFY:)			
Pregnancy Outcome					
DATE)OF DELIVE) Y:)				GESTATION)AGE)AT)DELIVE) Y:)	
		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					
	N	**Yes**			
LIVE)NO) MAL INFANT)	☐	☐			
FETAL DIST) ESS	☐	☐			
INT) A-UTE) INE)G) OWTH ETA)D ATION)	☐	☐			
NEONATAL COMPLICATIONS	☐	☐	IF YES, PLEASE)SPECIFY:)		
BI) TH DEFECT)NOTED?)	☐	☐	IF YES, PLEASE)SPECIFY:)		
e x: ☐ Male ☐ Female		**Birt Weig t:** __lbs _)oz.)or __) kg		**Length:** _____inches or ___) cm.)	
Apgar Score:h	Unknown:)	1)min:)		5)min:)	10)min:)

IGNATURE OF PERSON COMPLETING THIS FORM ..... DATE .....

MCN:h

Event-Specific Questionnaire for Patient or Male Patient of Pregnant Partner–
Pregnancy O tcomeN
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Dr gsafety@celgene.comN

Date _____3
Name of3Patient or Name of Male Patient of3Partner _____3

Please provide the outcome of3your or your partner's pregnancy.

☐ Normal baby

☐3Abnormal baby,3please specify defect_____3

☐3Therapeutic abortion
Please specify any abnormality of3the fetus if known:3_____3

☐ Spontaneous abortion or miscarriage
Please specify any abnormality of3the fetus if known:3_____3

Event-Specific Questionnaire for Primary Care Physician or Pediatrician – Infant Follow-up
Telephone: (908) 673-9667
Fax: (908) 673-9115
Email: Dr gsafety@celgene.comN

Date:3_____3
Name of3Patient or Name of Male Patient of3Partner (Mother)_____3
Name of Infant (if known) _____3

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

Anomalies Diagnosed Since Initial Report:3
_____3
☐ None

Developmental Assessment:3
☐ Normal
☐3Abnormal,3specify _____3

Infant Illnesses, Hospitalizations, Dr g Therapies:u

Infant Illnesses	**Hospitalized?u**	**Dr g Therapies**
	☐3Yes ☐3No	
	☐3Yes ☐3No	
	☐3Yes ☐3No	
	☐3Yes ☐3No	
	☐3Yes ☐3No	

SIGNATURE OF PERSON OMPLETING THIS FORMu **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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT C KANE
05/09/2012