This document is current as of June 1, 2013. It may not reflect the latest approved REMS.

Dispenser Certification Requirements

The following is a list of REMS with certification of dispensers and the requirements that dispensers must meet in order to become certified, based on the REMS document.

Adasuve

1. To become certified to dispense ADASUVE, each healthcare facility must enroll in the ADASUVE REMS Program.
2. Each healthcare facility must designate an authorized representative to complete enrollment on behalf of the healthcare facility.
3. Each healthcare facility must have immediate access on-site to equipment and personnel trained to provide advanced airway management, including intubation and mechanical ventilation.
4. Each healthcare facility must be equipped to provide immediate access on-site to a metered-dose inhaled and nebulized form of a short-acting beta-agonist bronchodilator (e.g., albuterol).
5. Each healthcare facility must:
    1. Screen patients, prior to treatment with ADASUVE, for a current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD) or other lung disease associated with bronchospasm, acute respiratory signs/symptoms (e.g. wheezing), and current use of medications to treat airways disease such as asthma or COPD; and examine patients (including chest auscultation) for respiratory abnormalities.
    2. Monitor patients at least every 15 minutes for a minimum of one hour following treatment with ADASUVE for symptoms and signs of bronchospasm (i.e.,vital signs and chest auscultation).
    3. Limit administration of ADASUVE to a single dose per patient within a 24-hour period.
6. Each healthcare facility must train relevant staff (e.g., staff involved in prescribing, dispensing or administering ADASUVE and monitoring patients after ADASUVE administration) on the safe use of ADASUVE, as described in the ADASUVE REMS Education Program. This training and ongoing training must be documented and is subject to audit.
7. Each healthcare facility must not dispense ADASUVE for outpatient use.
8. Each healthcare facility must renew its enrollment in the ADASUVE REMS Program within 3 years from the date of initial enrollment, and every three years thereafter.
9. Each healthcare facility must obtain ADASUVE from wholesalers/distributors that are enrolled in the ADASUVE REMS Program only.
10. Each healthcare facility must not sell, loan, or transfer any ADASUVE inventory to any other pharmacy, institution, distributor, or prescriber.
11. Each healthcare facility must establish procedures, protocols and/or order sets to help ensure compliance with the safe use conditions required in the ADASUVE REMS, and as described II.A.1.e through j., above. Healthcare facility procedures, protocols and/or order sets must be documented and are subject to audit.
12. The authorized representative must complete and sign the Healthcare Facility Enrollment Form to enroll the healthcare facility. In signing the Healthcare Facility Enrollment Form, the authorized representative is required to acknowledge that:
    1. The representative has reviewed the ADASUVE REMS Education Program and understands that treatment with ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest.

2. The representative understands that ADASUVE is contraindicated in patients with a current diagnosis or history of asthma, COPD or other lung disease associated with bronchospasm, and patients with acute respiratory signs/symptoms (e.g., wheezing) or who are taking medications to treat airways disease, such as asthma or COPD.
3. The healthcare facility will meet the requirements in b. through j. above.
4. The representative understands the importance of reporting events of bronchospasm that require intubation or other advanced airway management, in addition to any fatalities that occur following ADASUVE treatment. To report suspected adverse events contact Alexza Pharmaceuticals® at 1-800-284-0062, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch /report.htm.

Aranesp

1. To become specially certified, a Hospital Designee (eg, pharmacy director, Head of Hematology/Oncology, or other appointed designee) must enroll into the ESA APPRISE Oncology Program by doing the following:
    1. Complete the ESA APPRISE Oncology Program Training Module for Hospital Designees.
    2. Agree to assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in their hospital.
    3. Agree to establish or oversee the establishment of a system, order sets, protocols, or other measure designed to ensure that the hospital is in compliance with the ESA APPRISE Oncology Program, such that:
        1. Aranesp is only dispensed to patients with cancer after verifying:
            1. that the healthcare provider who prescribed Aranesp for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
            2. the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of Aranesp therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form prior to initiation of each new course of Aranesp therapy.
        2. If an HCP that prescribes Aranesp is not enrolled in the ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe Aranesp for patients with cancer.
    4. Oversee compliance with program monitoring and auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
    5. Maintain evidence of compliance with the ESA APPRISE Oncology Program for monitoring and auditing purposes, as follows:
        1. a list of each healthcare provider in my hospital who prescribes Aranesp for cancer patients
        2. documentation (ie, unique enrollment ID number) that each HCP in my hospital who prescribes Aranesp for patients with cancer is enrolled in the ESA APPRISE Oncology Program
        3. documentation of the risk:benefit discussion between certified prescriber and patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form for each cancer patient for whom an Aranesp prescription was filled
    6. Complete and sign the ESA APPRISE Oncology Program Enrollment Form for Hospitals and

submit it to the ESA APPRISE Oncology Program Call Center.

Caprelsa

1. To become certified to dispense CAPRELSA, each pharmacy must be enrolled in the CAPRELSA REMS Program.
2. To become certified, the authorized pharmacist on behalf of the pharmacy must agree to the following:
    1. I understand that only prescribers enrolled in the CAPRELSA REMS Program can prescribe Caprelsa® (vandetanib).
    2. The pharmacy must have a system in place to verify that the prescriber is enrolled in the CAPRELSA REMS Program each time CAPRELSA is dispensed. If the prescriber is not enrolled, CAPRELSA cannot be dispensed.
    3. All pharmacy staff and critical employees involved in the dispensing of CAPRELSA will be educated on the risks and requirements of the CAPRELSA REMS Program.
    4. The pharmacy will provide the Medication Guide each time CAPRELSA is dispensed.
    5. The pharmacy will ensure that it has adequate processes and procedures in place and that those processes and procedures are being followed for the CAPRELSA REMS Program.
    6. The pharmacy will maintain a system, records and documentation that can be audited to document compliance with the CAPRELSA REMS Program; including prescriber certification each time CAPRELSA is dispensed.
    7. Complete and sign the CAPRELSA Pharmacy Enrollment Form and submit it to the CAPRELSA REMS Program.

Entereg

1. The specially certified hospital will not transfer Entereg to any hospital not registered with the E.A.S.E. Program.
2. To register in the E.A.S.E. program, responsible hospital personnel must attest that:
    1. E.A.S.E. educational materials have been received by the hospital and distributed to healthcare professionals who are responsible for the ordering, prescribing, dispensing, or administering of Entereg;
    2. The hospital has systems, order sets, protocols, or other measures in place to ensure that Entereg is dispensed only to patients with evidence of safe use conditions. Please see Hospital Registration form.

Epogen / Procrit

1. To become specially certified, a Hospital Designee (eg, pharmacy director, Head of Hematology/Oncology, or other appointed designee) must enroll into the ESA APPRISE Oncology Program by doing the following:
    1. Complete the ESA APPRISE Oncology Program Training Module for Hospital Designees.
    2. Agree to assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in their hospital.
    3. Agree to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the ESA APPRISE Oncology Program, such that:
        1. Epogen/Procrit is only dispensed to patients with cancer after verifying:

        1. that the healthcare provider who prescribed Epogen/Procrit for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
        2. the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of Epogen/Procrit therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form prior to initiation of each new course of Epogen/Procrit therapy.
    2. If an HCP that prescribes Epogen/Procrit is not enrolled in the ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe Epogen/Procrit for patients with cancer.
4. Oversee compliance with program monitoring and auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
5. Maintain evidence of compliance with the ESA APPRISE Oncology Program for monitoring and auditing purposes, as follows:
    1. a list of each healthcare provider in my hospital who prescribes Epogen/Procrit for cancer patients
    2. documentation (ie, unique enrollment ID number) that each HCP in my hospital who prescribes Epogen/Procrit for patients with cancer is enrolled in the ESA APPRISE Oncology Program
    3. documentation of the risk:benefit discussion between certified prescriber and patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form for each cancer patient for whom an Epogen/Procrit prescription was filled
6. Complete and sign the ESA APPRISE Oncology Program Enrollment Form for Hospitals and submit it to the ESA APPRISE Oncology Program Call Center.

Isotretinoin

1. To become certified, the pharmacy must become registered and activated in the iPLEDGE program. To become registered and activated, each pharmacy must identify a “responsible site pharmacist” who completes the Pharmacy Enrollment Form and agrees to do the following before dispensing an isotretinoin prescription:
    1. Affirm that all pharmacists will comply with all iPLEDGE requirements:
        1. Know the risk and severity of fetal injury/birth defects caused by isotretinoin.
        2. Dispense only FDA-approved isotretinoin products and obtain isotretinoin only from iPLEDGE registered wholesalers.
        3. Do not sell, borrow, loan, or otherwise transfer isotretinoin in any manner to or from another pharmacy.
        4. Dispense only to qualified patients determined via authorization from the iPLEDGE web- or voice-based system for every isotretinoin prescription.
        5. Document the Risk Management Authorization (RMA) number on each prescription.
        6. Dispense no more than a 30-day supply (no refills).
        7. Dispense the isotretinoin Medication Guide with each prescription.
        8. Dispense prior to the “do not dispense to a patient after” date provided by the iPLEDGE program.
        9. Return to the manufacturer (or delegate) any unused product if registration is revoked or if the pharmacy chooses to not reactivate.

2. Re-activate pharmacy iPLEDGE registration annually.

Juxtapid

1. To become certified to dispense JUXTAPID, each pharmacy representative must agree to the following:
    1. To educate all pharmacy staff involved in the dispensing of JUXTAPID on the JUXTAPID REMS Program requirements.
    2. Put processes and procedures in place to verify, prior to dispensing JUXTAPID, that:
        1. the prescriber is certified in the JUXTAPID REMS Program.
        2. the JUXTAPID REMS Prescription Authorization Form is received for each new prescription.
    3. To be audited to ensure that all processes and procedures are in place and are being followed for the JUXTAPID REMS Program.
    4. To provide prescription data to the JUXTAPID REMS Program.

Kynamro

1. To become certified to dispense KYNAMRO, the authorized pharmacy representative must agree to the following:
    1. To educate all pharmacy staff involved in the dispensing of KYNAMRO on the KYNAMRO REMS Program requirements.
    2. Put processes and procedures in place to verify, prior to dispensing KYNAMRO, that:
        1. the prescriber is certified in the KYNAMRO REMS Program;
        2. the KYNAMRO REMS Prescription Authorization Form is received for each new prescription.
    3. To be audited to ensure that all processes and procedures are in place and are being followed for the KYNAMRO REMS Program.
    4. To provide prescription data to the KYNAMRO REMS program.

Letairis

1. Gilead will ensure that, to be certified, pharmacies, practitioners, and health care settings that dispense Letairis attest that they will:
    1. Receive and accept prescriber and patient enrollment forms only from the REMS Coordinating Center.
    2. Dispense LETAIRIS only to patients enrolled in the REMS program.
    3. Provide a Medication Guide to patients each time LETAIRIS is dispensed.
    4. For product that will be dispensed and shipped to the patient, confirm the drug shipment address with the patient.
    5. For women of childbearing potential (as defined in the Prescriber Enrollment and Agreement Form):
        1. Counsel patients on the risk of serious birth defects and the need to use highly reliable contraception (as defined in the Prescriber Enrollment and Agreement Form) during LETAIRIS treatment and for one month after treatment discontinuation.
        2. Inform patients of the need to complete a monthly pregnancy test and to inform their prescriber immediately if they suspect they may be pregnant.

3. Speak with each patient, or their prescriber, every month before dispensing LETAIRIS to obtain confirmation that pregnancy testing was completed.
4. Dispense LETAIRIS only as a 30-day supply and only upon completing the following process:
    1. Obtain confirmation from the patient that the pregnancy testing was completed.
    2. If unable to obtain confirmation from the patient that the pregnancy testing was completed, or if the patient cannot be reached, the certified dispenser will obtain confirmation from the patient's prescriber.
    3. If the patient's prescriber cannot confirm that the pregnancy testing was completed, the certified dispenser will:
        1. Remind the prescriber of his/her obligation to order and review monthly pregnancy tests.
        2. Ask the prescriber whether or not he/she authorizes the refill of LETAIRIS. The patient is eligible to receive a 30-day supply of LETAIRIS only if the prescriber authorizes the refill of LETAIRIS.
6. Call patients who discontinue LETAIRIS treatment, or their prescriber, to determine the reason for treatment discontinuation and record this information in the validated database.
7. Notify Gilead of any reports of adverse events and any reports of pregnancy and provide all available information needed for FDA Form 3500A.
8. Complete an inventory tracking log for every time LETAIRIS is dispensed.
9. Provide daily product dispensing data to the REMS Coordinating Center.

Lumizyme

1. To become certified into the Lumizyme ACE Program, healthcare facility representatives (director of pharmacy and/or infusion center representative [e.g., physician, head nurse, director of infusion center or director of education]) must enroll the healthcare facility in the Lumizyme ACE Program by submitting a completed Healthcare Facility Enrollment and Attestation Form attesting to the following:
    1. The Lumizyme ACE Program educational materials have been received by the healthcare facility and provided to the healthcare facility staff who are responsible for the ordering, dispensing and administration of Lumizyme.
    2. Healthcare facility staff has completed training that includes:
        1. The procedure for ordering Lumizyme.
        2. Procedures for dispensing Lumizyme only after completing Section 1 of the Lumizyme Infusion Confirmation Form (Healthcare Professional Preparing Lumizyme Infusion).
            1. In rare events such as vial breakage, patient weight change impacting the current dose, or a rescheduled infusion where Lumizyme vials cannot be shipped to the facility in time, vials designated for a patient enrolled in the Lumizyme ACE Program can be used for another patient also enrolled in the Lumizyme ACE Program at the same healthcare facility. Prior to using these vials, the healthcare facility must contact Genzyme to review the details of the event and to order replacement vials.
        3. Procedures for administering Lumizyme only after verifying that the patient is enrolled in the Lumizyme ACE Program, completing Section 2 of the Lumizyme Infusion Confirmation Form (Healthcare Professional Administering Lumizyme Infusion Therapy), faxing the completed Lumizyme Infusion Confirmation Form to Genzyme and affixing the sticker section of the form to the patient's file or scanning the form and saving it in the

patient's electronic medical record.

3. The healthcare facility has system procedures and/or other measures in place for appropriate monitoring of patients for early recognition of anaphylaxis and severe allergic reactions.
4. The healthcare facility has staff that is prepared to treat patients who experience anaphylaxis or severe allergic reactions to Lumizyme.
5. Healthcare facility staff understand that Lumizyme is indicated for patients 8 years and older with late (non-infantile) onset Pompe disease who do not have evidence of cardiac hypertrophy. The safety and efficacy of Lumizyme have not been evaluated in controlled clinical trials in infantile-onset patients or in late-onset disease patients less than 8 years of age.
6. Healthcare facility staff will dispense and administer Lumizyme only after ensuring each patient receives his/her designated drug by completing the Lumizyme Infusion Confirmation Form.
7. The healthcare facility understands that Genzyme may periodically perform audits at this healthcare facility to verify compliance with the procedures detailed in the Lumizyme ACE Program.

Pomalyst

1. To become a certified pharmacy, the pharmacy must agree to do the following before filling a POMALYST prescription:
    1. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.
    2. Dispense no more than a 4-week (28-day) supply, and require a new prescription from the patient prior to dispensing additional POMALYST.
    3. Dispense subsequent prescriptions only if there are 7 days or less remaining on an existing POMALYST prescription.
    4. Obtain a POMALYST REMS confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. The POMALYST REMS confirmation number may be obtained using the following procedure: 1. Enter the pharmacy identification number (NABP or DEA); 2. Enter the prescription authorization number written on the prescription; 3. Enter the number of capsules and milligram (mg) strength being dispensed; 4. Dispense or ship the prescribed POMALYST within 24 hours of obtaining and recording the POMALYST REMSTM confirmation number and confirmation date.
    5. Dispense POMALYST only after a POMALYST REMSTM confirmation number is obtained. If no confirmation is obtained, then no POMALYST is dispensed. Contact the patient's physician and Celgene for further instruction.
    6. Accept unused POMALYST (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.
    7. For each patient receiving treatment, retain a record of each POMALYST prescription dispensed and the corresponding completed Education and Counseling Checklist.
    8. Complete the checklist that applies to the patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.
    9. Provide counseling to patients and/or guardians of patients under 18 years of age receiving POMALYST treatment.
        1. Counsel all patients and guardians of patients under 18 years of age on the following:
            1. The benefits and risks of POMALYST therapy.
            2. Not sharing POMALYST medication.

3. Not donating blood while taking POMALYST, during dose interruptions, and for 4 weeks after stopping POMALYST.
4. Not to break, chew, or open POMALYST capsules.
5. Instructions on POMALYST dose and administration.
6. To read the POMALYST REMSTM program education materials and encourage compliance with the requirements.

2. In addition to above, counsel Females of Reproductive Potential on the following:
    1. The potential for embryo-fetal toxicity with exposure to POMALYST.
    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 POMALYST therapy is interrupted and for at least 4 weeks after therapy is discontinued.
    4. Obtaining a pregnancy test weekly during the first 4 weeks of POMALYST 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 POMALYST and notify their POMALYST prescriber immediately if they become pregnant or suspect they may be pregnant.
3. In addition to items listed for all patients above, counsel Males receiving POMALYST treatment about the potential for embryo-fetal toxicity with exposure to POMALYST and the importance of using barrier contraception by wearing a latex or synthetic condom when engaging in sexual intercourse with a female of reproductive potential even if the male receiving POMALYST has had a successful vasectomy.
    1. The need to not donate sperm while taking POMALYST, during dose interruptions, and for 4 weeks after stopping POMALYST.
4. Counsel the Parent or legal guardian of Female Child NOT of reproductive potential who is receiving POMALYST treatment about the need to inform their POMALYST prescriber when the child begins menses.

2. Before a certified pharmacy dispenses POMALYST, Celgene will train the appropriate pharmacy staff:
    1. About the POMALYST REMSTM program
    2. About the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to POMALYST if a pregnancy occurs.

Qsymia

1. To become certified, each pharmacy, including each pharmacy chain, each independent retail pharmacy, and each mail order pharmacy, must designate an Authorized Representative to internally coordinate and oversee the Qsymia REMS program. The Authorized Representative must complete the Qsymia REMS Pharmacy Training Program, knowledge assessment questions and sign an enrollment form acknowledging the following:
    1. the REMS requirement to provide a Medication Guide and the Risk of Birth Defects with Qsymia patient brochure to each patient each time Qsymia is dispensed
    2. a pharmacy management system is in place, and has been validated, to systematically direct that the Qsymia Medication Guide and the Risk of Birth Defects with Qsymia patient brochure be provided to each patient each time Qsymia is dispensed
    3. the pharmacy will refrain from reselling or transferring Qsymia to another pharmacy or distributor

4. that pharmacists and staff involved with the dispensing of Qsymia will be trained before dispensing Qsymia about the risks associated with Qsymia and the REMS requirement to provide a Medication Guide and the Risk of Birth Defects with Qsymia patient brochure to each patient each time Qsymia is dispensed
5. that all Qsymia retail prescriptions, regardless of the method of payment, will be processed through the pharmacy management system
6. that the pharmacy and pharmacy personnel will cooperate with pharmacy survey and audit requirements
7. that the pharmacy will provide quarterly Qsymia REMS compliance reports to VIVUS as described in the REMS supporting document
8. that the pharmacy will provide a list of Qsymia prescribers to VIVUS as described in the REMS supporting document

Revlimid

1. To become a certified pharmacy, the pharmacy must agree to do the following before filling a REVLIMID prescription:
    1. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.
    2. Dispense no more than a 4-week (28-day) supply, and require a new prescription from the patient prior to dispensing additional REVLIMID.
    3. Dispense subsequent prescriptions only if there are 7 days or less remaining on an existing REVLIMID prescription.
    4. Obtain a REVLIMID REMS™ confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. The REVLIMID REMS™ confirmation number may be obtained using the following procedure: 1.Enter the pharmacy identification number (NABP or DEA); 2.Enter the prescription authorization number written on the prescription; 3.Enter the number of capsules and milligram (mg) strength being dispensed; 4.Dispense or ship the prescribed REVLIMID within 24 hours of obtaining and recording the REVLIMID REMS™ confirmation number and confirmation date.
    5. Dispense REVLIMID only after a REVLIMID REMS™ program confirmation number is obtained. If no confirmation is obtained, then no REVLIMID is dispensed. Contact the patient's physician and Celgene for further instruction.
    6. Accept unused REVLIMID (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.
    7. For each patient receiving treatment, retain a record of each REVLIMID prescription dispensed and the corresponding completed REVLIMID REMS™ Education and Counseling Checklist.
    8. Complete the checklist that applies to the REVLIMID REMS™ program patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.
    9. Provide counseling to patients and/or guardians of patients under 18 years of age receiving REVLIMID treatment.
        1. Counsel all patients and guardians of patients under 18 years of age on the following:
            1. The benefits and risks of REVLIMID therapy.
            2. Not sharing REVLIMID medication
            3. Not donating blood while taking REVLIMID, during dose interruptions, and for 4 weeks after stopping REVLIMID.

4. Not to break, chew, or open REVLIMID capsules.
5. Instructions on REVLIMID dose and administration.
6. To read the REVLIMID REMS™ program education materials and encourage compliance with the requirements.

2. In addition to above, counsel Females of Reproductive Potential on the following:
    1. The potential for embryo-fetal toxicity with exposure to REVLIMID.
    2. Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse.
    3. Continuing to use 2 forms of birth control if REVLIMID therapy is interrupted and for at least 4 weeks after therapy is discontinued.
    4. Obtaining a pregnancy test weekly during the first 4 weeks of REVLIMID use, then a repeat pregnancy test every 4 weeks in females with regular menstrual cycles, and every 2 weeks in females with irregular menstrual cycles.
    5. The need to stop taking REVLIMID and notify their REVLIMID prescriber immediately if they become pregnant or suspect they may be pregnant.
3. In addition to items listed for all patients above, counsel Males receiving REVLIMID treatment about the potential for embryo-fetal toxicity with exposure to REVLIMID and the importance of using barrier contraception by wearing a latex or synthetic condom when engaging in sexual intercourse with a female of reproductive potential even if the male receiving REVLIMID has had a successful vasectomy.
    1. The need to not donate sperm while taking REVLIMID, during dose interruptions, and for 4 weeks after stopping REVLIMID.
4. Counsel the Parent or legal guardian of Female Child NOT of reproductive potential who is receiving REVLIMID treatment about the need to inform their REVLIMID prescriber when the child begins menses.

2. Before a certified pharmacy dispenses REVLIMID, Celgene will train the appropriate pharmacy staff:
    1. About the REVLIMID REMS™ program
    2. About the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to REVLIMID if a pregnancy occurs.

Rosiglitazone

1. To become certified to dispense rosiglitazone, each pharmacy must be enrolled in the Rosiglitazone REMS Program. To be certified, the pharmacy must agree to the following:
    1. To have a system in place to be able to verify that the prescriber (if the prescriber has prescribed rosiglitazone for outpatient or long-term care use) and patient are enrolled in the Rosiglitazone REMS Program prior to dispensing each time rosiglitazone is prescribed. If the patient and prescriber are not enrolled, rosiglitazone cannot be dispensed.
    2. To educate all pharmacy staff involved in the dispensing of rosiglitazone on the program requirements of the Rosiglitazone REMS Program.
    3. To provide a Medication Guide each time rosiglitazone is dispensed.
    4. To be audited to ensure that all processes and procedures are in place and are being followed for the Rosiglitazone REMS Program.

Sabril

1. Lundbeck Inc. will ensure that to be certified, each pharmacy does the following; pharmacies not complying may be de-enrolled by Lundbeck Inc:
    1. designates a representative who is trained on the REMS program
    2. dispenses Sabril only to patients who are enrolled in the REMS program, and whose continued eligibility has been established within the REMS
    3. obtains treatment forms and prescriptions only from the REMS coordinating center.
    4. obtains a dispensing authorization from the REMS coordinating center before dispensing the first Sabril prescription and before dispensing each refill.
    5. trains pharmacy staff on the REMS program procedures and REMS materials for dispensing
    6. agrees that the certified pharmacy may be audited by the FDA, Lundbeck Inc, or a third party designated by Lundbeck Inc.

Thalomid

1. To become a certified pharmacy, the pharmacy must agree to do the following before filling a THALOMID prescription:
    1. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.
    2. Obtain a confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. This may be obtained using the following procedure: 1. Enter the pharmacy identification number (NABP or DEA); 2. Enter the prescription authorization number written on the prescription; 3. Enter the number of capsules and milligram (mg) strength being dispensed; 4. Dispense or ship the prescribed THALOMID within 24 hours of obtaining and recording the THALOMID REMS™ confirmation number and confirmation date.
    3. Dispense THALOMID only after a THALOMID REMSTM confirmation number is obtained. If no confirmation is obtained, then no THALOMID is dispensed. Contact the patient’s physician and Celgene for further instruction.
    4. 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 THALOMID.
    5. Dispense subsequent prescriptions only if 7 days or fewer of therapy remain on the previous prescription.
    6. Dispense blister packs intact with enclosed prescribing information and Medication Guide; capsules cannot be repackaged.
    7. Not to redistribute or transfer THALOMID between pharmacies.
    8. Accept unused THALOMID (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.
    9. Allow Celgene to assess pharmacy knowledge of safe use and to perform on-site audits to monitor compliance of THALOMID REMS™ program.
    10. Educate all staff pharmacists dispensing THALOMID about the dispensing procedure for THALOMID.

Tikosyn

1. To be certified to dispense Tikosyn, each pharmacy and healthcare setting will be enrolled in the Tikosyn program. The enrollment process is comprised of the following steps that must be completed:

1. Each health care setting where Tikosyn is dispensed for use will designate a representative. The designated representative will enroll in the Tikosyn Program by submitting to Pfizer a completed Institution Certification Form, and agreeing to the following:
    1. I attest that the healthcare facility where Tikosyn is initiated or re-initiated can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation;
    2. I will ensure that all appropriate staff (including physicians, pharmacists, and telemetry nurses) are trained regarding the Tikosyn REMS program and will comply with all of the program requirements;
    3. I will establish or oversee the establishment of a system, order sets, protocols, or other measures to ensure appropriate dosing and monitoring;
    4. I will ensure that the pharmacy staff verifies that the prescribing healthcare provider is enrolled in the Tikosyn program prior to dispensing Tikosyn for inpatient use;
    5. I understand that, prior to patient discharge, the health care facility must either: provide a free 7-day (14-count) supply of Tikosyn and the Medication Guide to patients, or ensure the patient's take-home prescription is filled.
2. Each pharmacy where Tikosyn is dispensed will designate a representative. The designated representative will enroll in the Tikosyn Program by submitting to Pfizer a completed Tikosyn In Pharmacy Systems (T.I.P.S) Program Certification Form, agreeing to the following:
    1. I will ensure that all appropriate staff are trained and have read and understand the T.I.P.S. program materials.
    2. I will ensure that pharmacy staff will verify that the prescriber is certified in the Tikosyn program prior to dispensing each prescription, by accessing the system.
    3. I will ensure pharmacy staff stamp each prescription with the provided T.I.P.S. Stamp and initial and date the Tikosyn stamped prescription in the appropriate areas, verifying prescriber certification status.
    4. I will ensure that the Medication Guide is provided by the pharmacy staff to the patient with each prescription.
    5. I will ensure a copy of the above attestations is posted or otherwise made available to pharmacy staff to ensure that the pharmacy staff understands these special conditions for use of Tikosyn.

TIRF

1. To become certified to dispense TIRF medicines, each pharmacy must be enrolled in the TIRF REMS Access program.
2. Each pharmacy will be required to designate an authorized pharmacy representative (chain pharmacy) or authorized pharmacist (outpatient and inpatient pharmacies) to complete enrollment on behalf of the pharmacy(s).
3. Outpatient Pharmacies: The authorized pharmacist/pharmacy representative must complete the following requirements to enroll their outpatient pharmacy:
    1. Review the TIRF REMS Access Education Program (TIRF REMS Access Education Program) and successfully complete the Knowledge Assessment.
    2. Ensure the pharmacy enables its pharmacy management system to support communication with the TIRF REMS Access program system, using established telecommunication standards, and runs the standardized validation test transaction to validate the system enhancements.
    3. Complete and sign the Outpatient Pharmacy Enrollment Form or the Chain Pharmacy

Enrollment Form for groups of associated pharmacies. In signing the Outpatient Pharmacy Enrollment Form or Chain Pharmacy Enrollment Form, the authorized pharmacist is required to acknowledge the following:

1. I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the risks and benefits associated with TIRF medicines and the requirements of the TIRF REMS Access program for pharmacies.
2. I will ensure that all pharmacy staff who participate in dispensing TIRF medicines are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the TIRF REMS Access Education Program. This training should be documented and is subject to audit.
3. I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the 'List of TIRF Medicines available only through the TIRF REMS Access Program' in Attachment 1). Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.
4. I understand that TIRF medicines are contraindicated for use in opioid nontolerant patients.
5. I understand that the initial starting dose of TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.
6. I understand the importance of discussing the risks and benefits of TIRF medicines with patients and their caregivers, and in particular the importance of taking the drug as prescribed, not sharing with others, and proper disposal.
7. I understand that the product-specific Medication Guide must be given to the patient or their caregiver each time a TIRF medicine is dispensed.
8. I understand that TIRF medicines will not be dispensed without verifying through our pharmacy management system that the prescriber and pharmacy are enrolled and active, and that the patient has not been inactivated in the program.
9. I understand that ALL TIRF medicine prescriptions, regardless of the method of payment, must be processed through our pharmacy management system.
10. I understand that all dispensing locations must be enrolled in the TIRF REMS Access program to dispense TIRF medicines.
11. I understand that TIRF medicines can only be obtained from wholesalers/distributors that are enrolled in the TIRF REMS Access program.
12. I understand that our pharmacy will not sell, loan or transfer any TIRF medicine inventory to any other pharmacy, institution, distributor, or prescriber.
13. I understand that our pharmacy must re-enroll in the TIRF REMS Access program and successfully complete the enrollment requirements every two (2) years.
14. I understand that TIRF medicines are only available through the TIRF REMS Access program. I understand that the pharmacy must comply with the TIRF REMS Access program requirements for outpatient pharmacies.

4. Closed System Pharmacies: The authorized pharmacist/pharmacy representative must complete the following requirements to enroll their closed system pharmacy:
    1. Review the TIRF REMS Access Education Program (TIRF REMS Access Education Program) and successfully complete the Knowledge Assessment.
    2. Complete and sign the Closed System Pharmacy Enrollment Form. In signing the Closed System

Pharmacy Enrollment Form, the authorized closed system pharmacy representative is required to acknowledge the following:

1. I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the risks and benefits associated with TIRF medicines and the requirements of the TIRF REMS Access program for pharmacies.
2. I will ensure that all pharmacy staff who participate in dispensing TIRF medicines are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the TIRF REMS Access Education Program. This training should be documented and is subject to audit.
3. I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the 'List of TIRF Medicines available only through the TIRF REMS Access Program' in Attachment 1). Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.
4. I understand that TIRF medicines are contraindicated for use in opioid nontolerant patients.
5. I understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.
6. I understand the importance of discussing the risks and benefits of TIRF medicines with patients and their caregivers, and in particular the importance of taking the drug as prescribed, not sharing with others, and proper disposal.
7. I understand that the product-specific Medication Guide must be given to the patient or their caregiver each time a TIRF medicine is dispensed.
8. I understand that a TIRF medicine will not be dispensed without obtaining a TIRF REMS Access prescription authorization number issued by the TIRF REMS Access program prior to dispensing the prescription. A TIRF REMS Access prescription authorization number verifies that the prescriber and pharmacy are enrolled and active, and that the patient has not been inactivated from the program.
9. I understand that all dispensing locations must be enrolled in the TIRF REMS Access program to dispense TIRF medicines
10. I understand that TIRF medicines can only be obtained from wholesalers/distributors that are enrolled in the TIRF REMS Access program.
11. I understand that our pharmacy will not sell, loan or transfer any TIRF inventory to any other pharmacy, institution, distributor, or prescriber.
12. I understand that our pharmacy must re-enroll in the TIRF REMS Access program every two (2) years.
13. I understand that TIRF medicines are only available through the TIRF REMS Access program. I understand that the pharmacy must comply with the TIRF REMS Access program requirements for outpatient closed system pharmacies.

5. Inpatient Pharmacies: The authorized pharmacist must complete the following requirements to successfully enroll their inpatient pharmacy:
    1. Review the TIRF REMS Access Education Program (TIRF REMS Access Education Program) and successfully complete the pharmacy Knowledge Assessment.
    2. Complete and sign the Inpatient Pharmacy Enrollment Form. In signing the Inpatient Pharmacy Enrollment Form, the authorized pharmacist is required to acknowledge the following:

1. I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the benefits and risks associated with TIRF medicines and the requirements of the TIRF REMS Access program for pharmacies.
2. I will ensure that our inpatient pharmacists are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the TIRF REMS Access Education Program.
3. I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the 'List of TIRF Medicines available only through the TIRF REMS Access Program' in Attachment 1). Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.
4. I understand that TIRF medicines are contraindicated for use in opioid nontolerant patients.
5. I understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.
6. I understand that pharmacies within or associated with the healthcare facility that dispense to outpatients must be separately enrolled in and comply with the TIRF REMS Access program to dispense TIRF medicines to outpatients, as described in section B.2.d, above.
7. I understand that our inpatient pharmacy must not dispense TIRF medicines for outpatient use.
8. I understand that a prescriber who wants to discharge a patient with a TIRF medicine prescription, intended to be dispensed by an outpatient pharmacy, will be required to enroll in the TIRF REMS Access program, as described in section B.1 of this REMS.
9. I will establish, or oversee the establishment of, a system, order sets, protocols and/or other measures to help ensure appropriate patient selection and compliance with the requirements of the TIRF REMS Access program.
10. I understand that our pharmacy will not sell, loan or transfer any TIRF inventory to any other pharmacy, institution, distributor, or prescriber.
11. I understand that TIRF medicines can only be obtained from wholesalers/distributors that are enrolled in the TIRF REMS Access program.
12. I understand that our pharmacy must re-enroll in the TIRF REMS Access program every two (2) years.
13. I understand that TIRF medicines are available only through the TIRF REMS Access program. I understand and agree to comply with the TIRF REMS Access program requirements for inpatient pharmacies.

6. Pharmacies (authorized pharmacist) are required to re-enroll every two (2) years.

Tracleer

1. Outpatient Dispensing Tracleer will only be dispensed by outpatient pharmacies that are specially certified. Actelion will ensure that, to be certified, pharmacies are under legal contract and will:
    1. Receive and accept prescriber and patient enrollment forms only from PAH Pathways, the entity that administers TAP.
    2. Counsel patients 1. on the risks of Tracleer, including the risks of hepatotoxicity and serious birth

defects 2. on the need to complete a monthly liver function test and pregnancy test (for FCBP as defined in the Tracleer Product Information)

3. Counsel all FCBP on the need to use reliable contraception (as defined in the Tracleer Product Information) during Tracleer treatment and for one month after treatment discontinuation, and the need to inform their prescriber if they suspect they may be pregnant
4. For product that will be dispensed and shipped to the patient, confirm the drug shipment address with the patient
5. Dispense Tracleer only as 30-day supplies (except as described below) and require monthly refills
6. Dispense Tracleer only to patients enrolled in the REMS program
7. Provide a Medication Guide and Monthly Reminder Wallet card to patients each time Tracleer is dispensed
8. Speak with each patient, or their prescriber, every month to obtain confirmation that liver function testing and pregnancy testing was completed.
9. Dispense a 30-day supply of Tracleer (for patients not traveling outside the United States for more than 30 days) only upon completing the following process: 1. Obtain confirmation from the patient that the testing was completed. 2. If unable to obtain confirmation from the patient that the testing was completed, or if the patient cannot be reached, obtain confirmation from the patient's prescriber. 3. If the patient's prescriber cannot confirm that the required testing was completed, the certified pharmacy will: a. Remind the prescriber of his/her obligation to order and review monthly liver function tests and pregnancy tests (for FCBP) b. Ask the prescriber whether or not he/she authorizes the refill of Tracleer. The patient is eligible to receive a 30-day supply of Tracleer only if the prescriber authorizes the refill of Tracleer.
10. days, the following process must be completed: 1. The certified pharmacy is notified by an enrolled patient and/or certified prescriber of the need to fulfill a greater than 30-day supply due to the patient's extended travel outside the US. 2. The certified pharmacy contacts the patient and the prescriber to verify the need. The certified pharmacy explains the process to the patient, and tells them that the form (FRM-549-COP-US) will be sent to the certified prescriber for completion and submission. 3. The certified pharmacy provides the prescriber with a letter explaining the process, and the request form (FRM-549COP- US). 4. The certified prescriber completes the form and faxes it to the certified pharmacy. 5. The certified pharmacy reviews the form for completeness and contacts either the certified prescriber or the patient to obtain any additional information. 6. The medication is shipped to the patient, along with the Medication Guide and the required patient information sheet. 7. The certified pharmacy documents in their data management system that the patient met the criteria for the greater than 30-day supply due to foreign travel. This information is sent to Actelion as usual with the dispensed amount (in tablets), dose, and frequency captured. 8. The certified pharmacy contacts the prescriber for the monthly call in this situation to determine if safe-use conditions are being followed by the patient and prescriber. This is documented in the certified pharmacy data management system.
11. Call patients, who discontinue Tracleer treatment, or their prescriber, to determine the reason for treatment discontinuation and record this information for inclusion in the T.A.P. database
12. Notify Actelion of any reports of adverse events, including hepatotoxicity, and any reports of pregnancy.
13. Agree to collect and report to Actelion specific data requirements needed to ensure compliance with the Tracleer REMS program including shipment records for every time Tracleer is dispensed. Actelion maintains the data in the T.A.P. database.
14. Actelion will ensure that a designated representative of each certified pharmacy:
    1. is trained on the REMS program.

2. trains pharmacy staff on the REMS program procedures and REMS materials prior to dispensing Tracleer
3. agrees that the certified pharmacy may be audited by the FDA, Actelion, or a third party designated by Actelion

2. Inpatient Dispensing Actelion will ensure that Tracleer is only dispensed in the inpatient setting by certified hospitals.
    1. To be certified, a hospital must have an authorized designee complete and agree to the requirements in the Tracleer Access Program Hospital Certification Form and provide completed form to Actelion. The authorized designee acknowledges that:
        1. The hospital will establish systems, order sets, protocols, or other measures to limit the use of Tracleer as outlined below and to ensure appropriate liver function and pregnancy tests are performed.
        2. Tracleer will only be dispensed to inpatients who are under the supervision and care of a healthcare provider who has been certified in the Tracleer Access Program.
        3. Tracleer will only be dispensed to inpatients who are already enrolled in the Tracleer Access Program or who will be enrolled prior to discharge from this hospital.
        4. The hospital will dispense no more than a seven (7) day supply of Tracleer in a child-resistant container upon discharge of the patient.
        5. A Tracleer Medication Guide will be provided to the patient prior to discharge from this hospital. (Available for download at www.TRACLEERREMS.com)
        6. The hospital agrees to report adverse reactions to Actelion Pharmaceuticals US, Inc., including hepatotoxicity, and to report any pregnancy during treatment with Tracleer.
        7. The hospital agrees to re-certify every three (3) years.
        8. The hospital agrees to develop a system to track its compliance with the conditions above and provide information about its compliance to Actelion and/or the Food and Drug Administration upon request.

Tysabri

1. Pharmacies that dispense TYSABRI to infusion sites must enroll in the Tysabri TOUCH Prescribing Program by submitting a completed enrollment form and designating a person with appropriate authority to acknowledge the following:
    1. The pharmacy has received training and educational materials on the TOUCH Prescribing Program
    2. I understand that certified pharmacies may dispense TYSABRI only to authorized infusion sites
    3. I understand that, per the requirements of the TOUCH Prescribing Program, this certified pharmacy's compliance may be reviewed by the Food and Drug Administration (FDA) and/or audited by Biogen Idec, Elan Pharmaceuticals, Inc., and/or a third party designated by Biogen Idec or Elan Pharmaceuticals, Inc.
    4. I understand that noncompliance with the requirements of the TOUCH Prescribing Program may result in my pharmacy no longer being enrolled and termination of our participation in the program.
2. Infusion sites that dispense and administer TYSABRI must enroll in the TOUCH Prescribing Program by submitting a completed Infusion Site Enrollment Form and designating a person with appropriate authority to acknowledge the following:
    1. The infusion site has received training and educational materials on the TOUCH Prescribing Program

2. I understand that TYSABRI will be administered only to patients who are currently authorized in the TOUCH Prescribing Program. Patient authorization must be confirmed prior to each infusion by: 1. For TOUCH On-Line infusion sites: Patient Authorization Status must be “Authorized” or 2. For paper-based infusion sites: Receipt of current Notice of Patient Authorization and verification that no Notice of Patient Discontinuation is on file
3. I understand that each patient will receive a copy of the TYSABRI Patient Medication Guide prior to each infusion
4. I understand that a TYSABRI Pre-infusion Patient Checklist must be completed prior to each infusion. The Pre-infusion Patient Checklist must be submitted to Biogen Idec within 1 business day of the patient visit, regardless of whether or not the patient received the infusion, by: 1. For paper-based infusion sites: sending a copy of the completed Pre-infusion Patient Checklist to Biogen Idec. A copy must also be placed in the patient’s medical record 2. For TOUCH On-Line infusion sites: The infusion nurse can read, complete and submit the Pre-Infusion Patient Checklist directly in TOUCH On-Line
5. I understand that, per the requirements of the TOUCH Prescribing Program, this infusion site’s compliance with the REMS may be reviewed by FDA and/or audited by Biogen Idec, Elan Pharmaceuticals, Inc., and/or a third party designated by Biogen Idec or Elan Pharmaceuticals, Inc.
6. I understand that noncompliance with the requirements of the TOUCH Prescribing Program will result in de-enrollment of the infusion site.

Versacloz

1. The pharmacy enrollment process comprises the following steps that must be completed prior to dispensing Versacloz:
    1. The lead pharmacist will complete the Pharmacy Enrollment Form. In signing the Pharmacy Enrollment Form, the lead pharmacist indicates that all pharmacists with dispensing privileges at the pharmacy understand that Versacloz is only available to certified pharmacies after enrolling in the Versacloz REMS program, entitled Versacloz Patient Registry, and are aware of and attest to the following requirements:
        1. Review the Versacloz package insert and understand the risk of death associated with agranulocytosis or severe granulocytopenia/leukopenia prior to dispensing Versacloz.
        2. Enroll all applicable patients in the Versacloz Patient Registry. When enrolling a patient, healthcare providers will be matched with an enrolled pharmacy and be defined as an “affiliated treatment pair” by completing the appropriate section of the Patient Enrollment Form.
        3. Understand the recommendations for prescribing and monitoring as described in the package insert.
        4. Understand Versacloz should only be dispensed to a new patient after verifying an acceptable baseline WBC count (=3500/mm3) and ANC (=2000/mm3) test results and only after receiving a Patient Registration Number (PRN) from the Versacloz Patient Registry.
        5. Understand that no more than a 7 day supply of Versacloz should be dispensed to a patient who has been continually on clozapine treatment with a different clozapine formulation (i.e. clozapine tablets, clozapine orally disintegrating tablets) prior to initiating Versacloz but is not currently enrolled in the Versacloz Patient Registry, and understand that Versacloz should not be dispensed in such circumstances until verification that the patient

has an acceptable baseline WBC count (=3500/mm3) and ANC (=2000/mm3). They understand they should dispense Versacloz to a patient a second time only after receiving a valid PRN from the Versacloz Patient Registry.

6. Understand the importance of providing the Versacloz Patient Registry with all WBC count and test results for all enrolled patients within: • 7 days from blood draw to patients on weekly monitoring schedule • 14 days from blood draw to patients on bi weekly monitoring schedule • 28 days from blood draw to patients on monthly monitoring schedule
7. Understand the list of patients enrolled in the Versacloz Patient Registry will be used to verify a patient's rechallenge status against the Clozapine National Non-Rechallenge Masterfile. Furthermore, any patient permanently discontinued from Versacloz for meeting the non-rechallenge criteria (WBC count <2000/mm3 and/or ANC<1000mm3) will be reported to the Clozapine National Non-Rechallenge Masterfile.
8. Understand the Versacloz Patient Registry will be audited to monitor adherence to prescribing, monitoring and timeliness requirements and enrolled healthcare providers and pharmacies will be promptly notified of any discrepancies or missing information by Douglas Pharmaceuticals America LTD.

Zyprexa Relprevv

1. Lilly will ensure that to become enrolled the pharmacy and health-care setting staff have been educated about the requirements of the Zyprexa Relprevv Patient Care Program. The education and enrollment process is comprised of the following steps that must be completed:
    1. Each pharmacy and health-care setting where Zyprexa Relprevv is dispensed for use in other certain health-care settings will designate a representative who will review the Zyprexa Relprevv Patient Care Program Instruction Brochure. The designated representative will complete and sign the Pharmacy Registration Form or the Buy and Bill Registration Form. In signing the form, the representative is required to indicate that they understand and attest that:
        1. I have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;
        2. I will ensure that all appropriate pharmacy staff are trained and have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;
        3. I will ensure that all appropriate pharmacy staff understand that Zyprexa Relprevv can only be dispensed for use in certain health care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection;
        4. I will ensure that pharmacy staff will verify that the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry prior to dispensing each prescription/refill by accessing the system;
        5. I will ensure that pharmacy staff will not dispense Zyprexa Relprevv directly to patients;
        6. I will ensure pharmacy staff report the date of each Zyprexa Relprevv dispensing to the Zyprexa Relprevv Patient Care Program; and
        7. I understand that the Zyprexa Relprevv Patient Care Program coordinating center may contact the pharmacy to clarify information provided or obtain information about the patient.
    2. Each health-care setting where Zyprexa Relprevv is dispensed and administered to the patient will designate a representative who will review the Zyprexa Relprevv Patient Care Program

Instruction Brochure. The designated representative will complete and sign the Healthcare Facility Registration Form. In signing the form, the representative is required to indicate that they understand and attest that:

1. I have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;
2. I will ensure that all appropriate staff are trained and have read and understand the Zyprexa Relprevv Patient Care Program Instructions Brochure;
3. I will ensure that all appropriate staff understand that Zyprexa Relprevv can only be dispensed for use in certain health-care settings (e.g., hospitals, clinics) that have ready access to emergency response services that can allow for continuous patient monitoring for at least 3 hours post-injection;
4. I will ensure the health-care setting has systems, protocols, or other measures to ensure that Zyprexa Relprevv is only administered to patients enrolled in the program and that patients are continuously monitored for at least 3 hours post-injection for suspected PDSS;
5. I will ensure that appropriate staff will verify that the patient is enrolled in the Zyprexa Relprevv Patient Care Program Registry prior to each injection by accessing the system;
6. I will ensure that the Medication Guide is provided to the patient or the patient's legal guardian prior to each injection;
7. I will ensure that the appropriate staff monitors the patient continuously for at least 3 hours; and
8. I understand that the Zyprexa Relprevv Patient Care Program coordinating center may contact the health-care setting to clarify information provided or obtain information about the patient.