

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

## **ETASU Sub-headings**

The following is a list of the major subheadings found under the "Elements to Assure Safe Use" section of the REMS document.

### **Adasuve**

1. ADASUVE will only be dispensed in healthcare settings that are specially certified.

### **Aranesp**

1. Healthcare providers who both prescribe and dispense Aranesp for patients with cancer in private practice settings are specially certified.
2. Healthcare providers who prescribe Aranesp for patients with cancer in hospitals are specially certified.
3. Hospitals that dispense Aranesp for patients with cancer are specially certified.
4. Aranesp will be dispensed to patients with cancer with evidence or other documentation of safe-use conditions.

### **BTOD**

1. Safe use conditions
2. Monitoring

### **Caprelsa**

1. Healthcare providers who prescribe CAPRELSA are specially certified.
2. CAPRELSA will only be dispensed by pharmacies that are specially certified.

### **Entereg**

1. Drug Dispensed Only in Hospitals
2. Drug Dispensed in Specially Certified Hospitals
3. Drug Dispensed Only to Patients with Evidence of Safe-Use Conditions

### **Epogen / Procrit**

1. Healthcare providers who both prescribe and dispense Epogen/Procrit for patients with cancer in private practice settings are specially certified.
2. Healthcare providers who prescribe Epogen/Procrit for patients with cancer in hospitals are specially certified.
3. Hospitals that dispense Epogen/Procrit for patients with cancer are specially certified.
4. Epogen/Procrit will be dispensed to patients with cancer with evidence or other documentation of safe-use conditions.

## **ER/LA Opioids**

1. Training will be made available to healthcare providers who prescribe ER/LA opioid analgesics.

## **Extraneal**

1. Extraneal will only be dispensed to patients with documentation of safe-use conditions

## **Gattex**

1. Healthcare providers who prescribe GATTEX will receive training.

## **Isotretinoin**

1. Healthcare providers who prescribe isotretinoin are specially certified in the iPLEDGE Program.
2. Isotretinoin will only be dispensed by pharmacies that are specially certified in the iPLEDGE program.
3. Isotretinoin sponsors will ensure that isotretinoin will only be dispensed to patients enrolled in the iPLEDGE Program with evidence or other documentation of safe-use conditions.
4. Isotretinoin sponsors will maintain a centralized pregnancy registry for iPLEDGE enrolled female patients who become pregnant and consent to participate in a root cause analysis.

## **Juxtapid**

1. Healthcare Providers (HCP) who prescribe JUXTAPID are specially certified.
2. JUXTAPID will be dispensed only by specially certified pharmacies.
3. JUXTAPID will be dispensed only to patients with evidence or other documentation of safe-use conditions.

## **Kynamro**

1. Healthcare Providers (HCP) who prescribe KYNAMRO are specially certified.
2. KYNAMRO will be dispensed only by specially certified pharmacies.
3. KYNAMRO will be dispensed only to patients with evidence or other documentation of safe-use conditions.

## **Letairis**

1. Healthcare providers who prescribe LETAIRIS will be specially certified under 505-1(f)(3)(A).
2. Pharmacies, practitioners, and health care settings that dispense LETAIRIS (dispensers) will be specially certified under 505-1(f)(3)(B).
3. LETAIRIS will be dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D):

## **Lotronex**

1. Healthcare providers who prescribe LOTRONEX will be specially certified.
2. Each patient prescribed LOTRONEX must have signed a Patient Acknowledgement Form for

documentation of safe-use conditions.

3. Pharmacists will only dispense LOTRONEX to patients with documentation of safe-use conditions:

## **Lumizyme**

1. Healthcare providers who prescribe Lumizyme will be specially certified.
2. Lumizyme will only be dispensed by healthcare facilities that are specially certified
3. Lumizyme will be dispensed to patients with evidence or other documentation of safe-use conditions. Genzyme will ensure that each patient treated with Lumizyme is enrolled in the Lumizyme ACE Program.

## **Mifeprex**

1. Healthcare providers who prescribe MIFEPREX will be specially certified.
2. MIFEPREX will be dispensed only in certain health care settings, specifically clinics, medical offices, and hospitals.
3. MIFEPREX will only be dispensed to patients with documentation of safe use conditions.

## **mycophenolate**

1. Healthcare providers who prescribe mycophenolate will receive training.
2. Mycophenolate sponsors will maintain a centralized pregnancy registry for females who become pregnant and consent to participate.

## **Pomalyst**

1. Healthcare providers who prescribe POMALYST are specially certified.
2. POMALYST will only be dispensed by pharmacies that are specially certified.
3. Celgene will ensure that POMALYST will only be dispensed to patients enrolled in the POMALYST REMSTM program with evidence or other documentation of safe-use conditions.
4. Female patients or female partners of male patients receiving POMALYST who report a pregnancy that occurred during POMALYST therapy will be enrolled in the POMALYST Pregnancy Exposure Registry.

## **Qsymia**

1. Training will be provided to healthcare providers who prescribe Qsymia
2. Pharmacies that dispense Qsymia will be specially certified

## **Revlimid**

1. Healthcare providers who prescribe REVLIMID are specially certified.
2. REVLIMID will only be dispensed by pharmacies that are specially certified.
3. Celgene will ensure that REVLIMID® will only be dispensed to patients enrolled in the REVLIMID REMS™ program with evidence or other documentation of safe-use conditions.
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.

## **Rosiglitazone**

1. Healthcare providers who prescribe rosiglitazone for outpatient or long-term care use are specially certified
2. Rosiglitazone will be dispensed only by specially certified pharmacies.
3. Rosiglitazone will only be dispensed to patients with evidence or other documentation of safe-use conditions

## **Sabril**

1. Healthcare providers who prescribe Sabril will be specially certified under 505-1 (f)(3)(A).
2. Pharmacies that dispense Sabril are specially certified by Lundbeck Inc, under 5051(f)(3)(B).
3. Sabril will be dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D):
4. Each patient using the drug is enrolled in a registry under 505-1(f)(3)(F)

## **Soliris**

1. Healthcare providers who prescribe Soliris are specially certified.
2. Safe use conditions
3. Monitoring

## **Suboxone Sublingual Tablets**

1. Safe use conditions
2. Monitoring

## **Subutex**

1. Safe use conditions
2. Monitoring

## **Thalomid**

1. Healthcare providers who prescribe THALOMID are specially certified.
2. THALOMID will only be dispensed by pharmacies that are specially certified.
3. THALOMID will only be dispensed to patients enrolled in the THALOMID REMSTM program with evidence or other documentation of safe use conditions.
4. Female patients or female partners of male patients receiving THALOMID who report a pregnancy that occurred during THALOMID therapy will be enrolled in a THALOMID Pregnancy Exposure Registry.

## **Tikosyn**

1. Healthcare providers who prescribe Tikosyn will be specially certified
2. Tikosyn will only be dispensed by pharmacies and health care settings that are specially certified

## **TIRF**

1. Healthcare providers who prescribe TIRF medicines for outpatient use are specially certified.
2. TIRF medicines will only be dispensed by pharmacies that are specially certified.
3. TIRF medicines will only be dispensed for outpatient use with evidence or other documentation of safe-use conditions.

## **Tracleer**

1. Tracleer will only be prescribed by healthcare professionals who are certified by Actelion under 505-1(f)(3)(A)
2. Tracleer will only be dispensed by pharmacies, practitioners, hospitals and health care settings (dispensers) that are specially certified by Actelion under 505-1(f)(3)(B).
3. Tracleer will only be dispensed for outpatients use with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D):

## **Truvada**

1. Gilead Sciences, Inc., will ensure that training and education through the TRUVADA for a PrEP Indication Healthcare Professional Education Program is available to healthcare providers who prescribe TRUVADA for a PrEP indication.

## **Tysabri**

1. Healthcare providers who prescribe TYSABRI are specially certified.
2. TYSABRI will be dispensed only by pharmacies and infusion sites that are specially certified.
3. TYSABRI will be dispensed to patients with evidence or other documentation of safe-use conditions.

## **Versacloz**

1. Healthcare providers who prescribe Versacloz are specially certified.
2. Pharmacies that dispense Versacloz are specially certified.
3. Versacloz may be dispensed to patients with documentation of safe-use conditions.
4. Each patient using Versacloz is subject to certain monitoring.
5. Each patient using Versacloz is enrolled in a registry.

## **Zyprexa Relprevv**

1. Healthcare providers who prescribe Zyprexa Relprevv are specially certified under 505-1(f)(3)(A).
2. Zyprexa Relprevv will only be dispensed by pharmacies and health-care settings under FDCA 505-1(f)(3)(C) who are specially certified under FDCA 505-1(f)(3)(B).
3. Zyprexa Relprevv will be dispensed to patients with evidence or other documentation of safe-use conditions under FDCA 505-1(f)(3)(D).
4. Each patient using Zyprexa Relprevv will be subject to certain monitoring under 505-1(f)(3)(E).
5. Each patient using the drug will be enrolled in a registry under 505-1(f)(3)(F).