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

REMS Goals

The following is a list of goals from the REMS document.

Actemra

1. The goal of the ACTEMRA REMS is:
    1. To inform healthcare providers about the serious risks associated with ACTEMRA.

Adasuve

1. The goal of the ADASUVE™ REMS is to mitigate the negative outcomes associated with ADASUVE-induced bronchospasm by:
    1. Ensuring that ADASUVE is dispensed only in certified healthcare settings that have immediate access on-site to equipment and personnel trained to provide advanced airway management, including intubation and mechanical ventilation.
    2. Informing healthcare professionals in these settings that ADASUVE can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest.
    3. Informing healthcare professionals in these settings about the safe use of ADASUVE, including appropriate patient selection, monitoring, and management.

Ampyra

1. The goals of the AMPYRA REMS are:
    1. To inform healthcare providers about the risk of drug-associated seizures in patients treated with AMPYRA.
    2. To inform healthcare providers about the change of the established name from fampridine to dalfampridine.

Androgel

1. To inform patients about the serious risks associated with the use of AndroGel (testosterone gel) 1%.

Androgel 1.62%

1. To inform patients about the serious risks associated with the use of AndroGel (testosterone gel) 1.62%.

Aranesp

1. To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Aranesp by educating them on the risks of Aranesp.

Aranesp

1. For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs {erythropoiesis stimulating agents}) Oncology Program, is to mitigate the risk of shortened overall survival and/or increased risk of tumor progression or recurrence.

Axiron

1. To inform patients about the serious risks associated with the use of AXIRON® (testosterone) topical solution.

Brilinta

1. The goals of the BRILINTA REMS are:
    1. To inform healthcare professionals and patients of the serious risks associated with BRILINTA, particularly the increased risk of bleeding.
    2. To inform healthcare professionals and patients that the daily maintenance dose of aspirin, co-administered with BRILINTA, should not exceed 100 mg.

BTOD

1. The goals of the Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) REMS are to:
    1. Mitigate the risks of accidental overdose, misuse, and abuse
    2. Inform patients of the serious risks associated with buprenorphine-containing products

Bydureon

1. To inform healthcare professionals about the risk of acute pancreatitis (including necrotizing and hemorrhagic pancreatitis) and the potential risk of medullary thyroid carcinoma associated with BYDUREON.

Caprelsa

1. The goals of the CAPRELSA REMS are:
    1. to educate prescribers about the risk, appropriate monitoring, and management of QT prolongation to help minimize the occurrence of Torsades de pointes and sudden death associated with CAPRELSA.
    2. to inform patients about the serious risks associated with CAPRELSA.

Chantix

1. The goal of this REMS is to inform patients about the serious risks associated with the use of CHANTIX, including the potential risk of serious neuropsychiatric symptoms in patients taking CHANTIX.

Eliquis

1. The goal of the ELIQUIS REMS is to inform healthcare providers (HCPs) about:
    1. the increased risk of thrombotic events, including stroke, in patients with nonvalvular atrial fibrillation when discontinuing ELIQUIS without introducing an adequate alternative anticoagulant
    2. the importance of following the recommendations in the US Prescribing Information (USPI) on how to convert patients with nonvalvular atrial fibrillation from ELIQUIS to warfarin or other anticoagulants.

Entereg

1. To reduce the risk of myocardial infarction observed with longer use, Entereg (alvimopan) will be used only for short-term use (not to exceed 15 doses) in inpatient settings.

Epogen / Procrit

1. To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Epogen/Procrit by educating them on the risks of Epogen/Procrit.
2. For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs {erythropoiesis stimulating agents}) Oncology Program, is to mitigate the risk of shortened overall survival and/or increased risk of tumor progression or recurrence.

ER/LA Opioids

1. The goal of this REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of extended-release or long-acting (ER/LA) opioid analgesics while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death.

Extraneal

1. To mitigate the risk of morbidity and mortality associated with the use of non-specific glucose monitors and test strips in patients using Extraneal by:
    1. Informing the dialysis clinic staff managing the patient’s treatment (such as peritoneal dialysis nurses) about the drug-device interaction and the potential for falsely elevated blood glucose readings in patients using Extraneal.
    2. Informing patients of the drug-device interaction and the need to alert health care providers of this interaction whenever they receive treatment outside of a dialysis clinic.

Forteo

1. To mitigate the potential risk of osteosarcoma associated with FORTEO by:
    1. alerting and warning healthcare providers and patients about the potential risk
    2. informing healthcare providers of the 2-year maximum lifetime duration of treatment with FORTEO and proper patient selection
    3. informing and educating healthcare providers and patients about the voluntary FORTEO Patient Registry.

Fortesta

1. The goal of this REMS is to inform patients about the serious risks associated with the use of FORTESTA (testosterone) Gel.

Gattex

1. To inform prescribers and patients about the risks of possible acceleration of neoplastic growth and enhancement of colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disorders associated with GATTEX.

Gilenya

1. The goal of the GILENYATM (fingolimod) REMS is:
    1. To inform healthcare providers about the serious risks of GILENYA (fingolimod) including bradyarrhythmia and atrioventricular block at treatment initiation, infections, macular edema, respiratory effects, hepatic effects, and fetal risk.

Isotretinoin

1. The goals of the isotretinoin risk evaluation and mitigation strategy are:
    1. To prevent fetal exposure to isotretinoin
    2. To inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions

Juxtapid

1. The goals of the JUXTAPID REMS Program are:
    1. To educate prescribers about:
        1. the risk of hepatotoxicity associated with the use of JUXTAPID; and
        2. the need to monitor patients during treatment with JUXTAPID as per product labeling.
    2. To restrict access to therapy with JUXTAPID to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH).

Krystexxa

1. The goal of the KRYSTEXXA Risk Evaluation and Mitigation Strategy (REMS) is:
    1. To inform healthcare providers about anaphylaxis, infusion reactions, and contraindication of use of KRYSTEXXA in patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency.

Kynamro

1. The goals of the KYNAMRO REMS Program are:
    1. To educate prescribers about:
        1. the risk of hepatotoxicity associated with the use of KYNAMRO; and
        2. the need to monitor patients during treatment with KYNAMRO as per product labeling.
    2. To restrict access to therapy with KYNAMRO to patients with a clinical or laboratory diagnosis

consistent with homozygous familial hypercholesterolemia (HoFH).

Letairis

1. The risk minimization goals of the LETAIRIS Risk Evaluation and Mitigation Strategy (REMS) are:
    1. To encourage informed benefit-risk decisions regarding the use of LETAIRIS
    2. To minimize the risk of fetal exposure and adverse fetal outcomes in women of childbearing potential prescribed LETAIRIS
        1. Women who are pregnant must not be prescribed LETAIRIS
        2. Women taking LETAIRIS must not become pregnant

Lotronex

1. To mitigate the risk of ischemic colitis (IC) and serious complications of constipation (CoC) associated with LOTRONEX (alosetron hydrochloride) by ensuring that LOTRONEX is used in only severely affected patients for whom benefits exceed the risks.
2. To ensure that the risk of IC and serious CoC with the use of LOTRONEX are communicated to patients, pharmacists, and prescribers.

Lumizyme

1. To mitigate the potential risk of rapid disease progression in infantile-onset Pompe disease patients and patients with late (non-infantile) onset disease less than 8 years of age for whom the safety and effectiveness of Lumizyme have not been evaluated.
2. To ensure that the known risks of anaphylaxis and severe allergic reactions associated with the use of Lumizyme are communicated to patients and prescribers, and to ensure that the potential risks of severe cutaneous and systemic immune mediated reactions to Lumizyme are communicated to patients and prescribers.

Metoclopramide

1. The goal of this REMS is to minimize the risk of tardive dyskinesia associated with the long-term use of Metoclopramide Oral Solution.

Mifeprex

1. To provide information to patients about the benefits and risks of MIFEPREX before they make a decision whether to take the drug.
2. To minimize the risk of serious complications by requiring prescribers to certify that they are qualified to prescribe MIFEPREX and are able to assure patient access to appropriate medical facilities to manage any complications.

Multaq

1. To prevent Multaq® use in patients with:
    1. Symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure

    2. Permanent atrial fibrillation (AF) that will not or cannot be cardioverted into normal sinus rhythm
2. To inform healthcare professionals and patients about the serious risks of Multaq®, including:
    1. Increased risk of cardiovascular death in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure
    2. Increased risk of cardiovascular death, heart failure and stroke in patients with permanent AF
    3. Signs and symptoms of liver injury and hepatic failure

Mycophenolate

1. The goals of the Mycophenolate REMS are:
    1. To prevent unplanned pregnancy in patients using mycophenolate and to minimize fetal exposure to mycophenolate by informing prescribers and females of reproductive potential about:
        1. the increased risk of first trimester pregnancy loss and congenital malformation associated with exposure to mycophenolate during pregnancy; and
        2. the importance of pregnancy prevention and planning
    2. To minimize the risks associated with fetal exposure to mycophenolate by collecting information on pregnancy outcomes through the Mycophenolate Pregnancy Registry
    3. To inform patients about the serious risks associated with mycophenolate.

Nplate

1. To inform healthcare providers about the risks of progression of myelodysplastic syndromes (MDS) to acute myelogenous leukemia (AML), thrombotic/thromboembolic complications, bone marrow reticulin formation, bone marrow fibrosis, worsened thrombocytopenia after cessation of Nplate®, and Nplate medication errors associated with serious outcomes.

Nulojix

1. The goals of the NULOJIX REMS are:
    1. To inform healthcare providers of the increased risk of post-transplant lymphoproliferative disorder (PTLD), predominantly in the central nervous system (CNS), associated with NULOJIX
    2. To inform healthcare providers of the increased risk of progressive multifocal leukoencephalopathy (PML), a CNS infection, associated with NULOJIX
    3. To inform patients of the serious risks associated with NULOJIX

Omontys

1. To inform healthcare professionals that OMONTYS Injection is indicated only for use in the treatment of patients with anemia due to chronic kidney disease on dialysis.
2. To inform healthcare professionals of the serious risks associated with the use of OMONTYS Injection including potentially fatal cardiovascular and/or thromboembolic adverse events, and the increased risk of these events in non-dialysis patients.

Pomalyst

1. The goals of the POMALYST risk evaluation and mitigation strategy are as follows:

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

Potiga

1. The goal of the REMS for POTIGA is to inform healthcare professionals of the risk of urinary retention and the symptoms of acute urinary retention in patients taking POTIGA.

Prolia

1. To inform healthcare providers (HCP) about the risks of serious infections, dermatologic adverse reactions, and suppression of bone turnover, including osteonecrosis of the jaw, associated with Prolia® (denosumab).
2. To inform patients about the serious risks associated with the use of Prolia.

Promacta

1. To inform healthcare providers about the risks of hepatotoxicity, bone marrow reticulin formation and the risk for bone marrow fibrosis, thrombotic/thromboembolic complications, and hematologic malignancies associated with the use of PROMACTA

Qsymia

1. To inform prescribers and females of reproductive potential about:
    1. the increased risk of congenital malformations, specifically orofacial clefts, in infants exposed to Qsymia during the first trimester of pregnancy
    2. the importance of pregnancy prevention for females of reproductive potential receiving Qsymia
    3. the need to discontinue Qsymia immediately if pregnancy occurs.

Revlimid

1. The goals of the REVLIMID risk evaluation and mitigation strategy are as follows:
    1. To prevent the risk of embryo-fetal exposure to REVLIMID.
    2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for REVLIMID.

Rosiglitazone

1. The goals of the Rosiglitazone REMS Program for the rosiglitazone-containing medicines (hereafter referred to as rosiglitazone) are:
    1. To restrict access to rosiglitazone so that only prescribers who acknowledge the potential increased risk of myocardial infarction associated with the use of rosiglitazone are prescribing rosiglitazone.
    2. To restrict access to patients who have been advised by a healthcare provider about the potential increased risk of myocardial infarction associated with the use of rosiglitazone and are one of the following:

1. either already taking rosiglitazone or
2. if not already taking rosiglitazone, they are unable to achieve glycemic control on other medications and, in consultation with their healthcare provider, have decided not to take pioglitazone for medical reasons

Sabril

1. The goals of the REMS are:
    1. To reduce the risk of a Sabril-induced vision loss while delivering benefit to the appropriate patient populations;
    2. To ensure that all patients receive a baseline ophthalmologic evaluation; 50% of patients will receive within 2 weeks of starting Sabril and 100% within 4 weeks;
    3. To discontinue Sabril therapy in patients who experience an inadequate clinical response;
    4. To detect Sabril-induced vision loss as early as possible;
    5. To ensure regular vision monitoring to facilitate ongoing benefit-risk assessments; and
    6. To inform patients/parent or legal guardian of the serious risks associated with Sabril, including vision loss and increased risk of suicidal thoughts and behavior.

Soliris

1. The goals of the REMS are:
    1. To mitigate the occurrence and morbidity associated with meningococcal infections
    2. To educate Healthcare Professionals (HCP) and Patients (or Caregivers, or Legal Guardians) regarding:
        1. the increased risk of meningococcal infections with Soliris
        2. the early signs of invasive meningococcal infections, and
        3. the need for immediate medical evaluation of signs and symptoms consistent with possible meningococcal infections

Stelara

1. To evaluate and mitigate the potential risks of serious infections and malignancy, and reversible posterior leukoencephalopathy syndrome (RPLS) associated with STELARA® by:
    1. alerting and warning healthcare providers about the risks

Suboxone Sublingual Film

1. The goals of the SUBOXONE film risk evaluation and mitigation strategy are to:
    1. Mitigate the risks of accidental overdose, misuse and abuse
    2. Inform patients of the serious risks associated with SUBOXONE film

Suboxone Sublingual Tablets

1. The goals of the SUBOXONE tablet risk evaluation and mitigation strategy are to:
    1. Mitigate the risks of accidental overdose, misuse, and abuse
    2. Inform patients of the serious risks associated with SUBOXONE tablets

Subutex

1. The goals of the SUBUTEX tablet risk evaluation and mitigation strategy are to:
    1. Mitigate the risks of accidental overdose, misuse, and abuse
    2. Inform patients of the serious risks associated with SUBUTEX tablet

Tapentadol

1. The goal of this REMS is to communicate the key safety information on TRADENAME™ (tapentadol) in order to reduce the risks of serious adverse events, inappropriate use, and inappropriate storage and disposal.

Tasigna

1. The goals of the REMS are to:
    1. Minimize the occurrence of QT prolongation and its potential cardiac sequelae.
    2. Reduce medication errors involving drug-food interactions and incorrect dosing intervals.
    3. Minimize potential interactions (drug-drug and disease-drug).
    4. Inform patients about the serious risks associated with Tasigna treatment.
    5. Inform healthcare providers about the serious risks associated with the use of Tasigna, including QT prolongation.

Testim

1. The goal of this REMS is to inform patients about the serious risks associated with the use of TESTIM® 1% (testosterone gel).

Testosterone Gel

1. The goal of this REMS is to inform patients about the serious risks associated with the use of testosterone gel.

Thalomid

1. The goals of the THALOMID risk evaluation and mitigation strategy are as follows:
    1. To prevent the risk of embryo-fetal exposure to THALOMID.
    2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID.

Tikosyn

1. To mitigate the risk of Tikosyn induced arrhythmia by:
    1. Ensuring that Tikosyn is prescribed only by certified prescribers, dispensed only by certified dispensers, and dispensed for use only with documentation of safe use conditions;
    2. Educating health care providers about the risks and the need to initiate and re-initiate therapy in a health care facility that can provide calculations of creatinine clearance, continuous electrocardiographic monitoring, and cardiac resuscitation;

3. Informing patients about the serious risks associated with Tikosyn therapy.

TIRF

1. The goals of the TIRF REMS Access program are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:
    1. Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients.
    2. Preventing inappropriate conversion between TIRF medicines.
    3. Preventing accidental exposure to children and others for whom it was not prescribed.
    4. Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose of TIRF medicines.

Tracleer

1. The goals of the Tracleer risk evaluation and mitigation strategy are as follows:
    1. To enable informed risk-benefit decisions for treating patients with Tracleer.
    2. To minimize the risk of hepatotoxicity in patients who are exposed to Tracleer.
    3. To minimize the risk of fetal exposures in female patients who are exposed to Tracleer.
    4. To educate prescribers, patients, hospitals, and pharmacies on the safe-use conditions for Tracleer.

Truvada

1. The goals of the REMS for TRUVADA for a Pre-Exposure Prophylaxis (PrEP) Indication are:
    1. To inform and educate prescribers, other healthcare professionals, and individuals at high risk for acquiring HIV-1 infection about:
        1. The importance of strict adherence to the recommended dosing regimen
        2. The importance of regular monitoring of HIV-1 serostatus to avoid continuing to take TRUVADA for a PrEP indication, if seroconversion has occurred, to reduce the risk of development of resistant HIV-1 variants
        3. The fact that TRUVADA for a PrEP indication must be considered as only part of a comprehensive prevention strategy to reduce the risk of HIV-1 infection and that other preventive measures should also be used

Tysabri

1. The goals of the Tysabri REMS are:
    1. To inform prescribers, infusion center healthcare providers, and patients about the risk of progressive multifocal leukoencephalopathy (PML) associated with TYSABRI including the increased risk of PML with longer treatment duration, prior immunosuppressant use and the presence of anti-JCV antibodies.
    2. To warn against concurrent use with antineoplastic, immunosuppressant, or immunomodulating agents, and in patients who are immunocompromised.
    3. To promote early diagnosis of PML and timely discontinuation of TYSABRI in the event of suspected PML.

Versacloz

1. To minimize the risk of agranulocytosis associated with the use of Versacloz by:
    1. Ensuring compliance with the monitoring schedule for White Blood Cell Count (WBC) and Absolute Neutrophil Count (ANC) prior to dispensing Versacloz
    2. Preventing re-exposure of patients who have previously experienced agranulocytosis or severe granulocytopenia/leukopenia with any clozapine products.

Vibativ

1. The goal of the VIBATIV REMS is to avoid unintended exposure of pregnant women to VIBATIV by:
    1. Educating healthcare professionals (HCPs) and patients on the potential risk of fetal developmental toxicity if women are exposed to VIBATIV while pregnant.
    2. Informing HCPs that a serum pregnancy test should be performed before initiating therapy with VIBATIV in women of childbearing potential.
    3. Informing HCPs that women of childbearing potential, including those being treated in the outpatient setting, should be counseled about pregnancy prevention and use of effective contraception during VIBATIV use.
    4. Informing HCPs and patients about the Pregnancy Registry for patients exposed to VIBATIV during pregnancy.

Victoza

1. To inform providers about the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis (including necrotizing pancreatitis) associated with VICTOZA®.

Vivitrol

1. The goal of this REMS is to inform patients about the serious risks associated with the use of VIVITROL, including injection site reactions.

Xarelto

1. The goals of the XARELTO® REMS are:
    1. To inform healthcare professionals (HCPs) that discontinuing XARELTO without introducing an adequate alternative anticoagulant places nonvalvular atrial fibrillation patients at an increased risk of thrombotic events, including stroke, and to follow recommendations in the US Prescribing Information (USPI) on how to convert nonvalvular atrial fibrillation patients from XARELTO to warfarin or other anticoagulants.
    2. To inform healthcare professionals that XARELTO (15 or 20 mg tablets) should be taken with the evening meal.

Xeljanz

1. The goal of the XELJANZ REMS is to inform healthcare providers and patients about the serious risks associated with XELJANZ treatment.

Xenazine

1. The goal of the REMS for Xenazine is:
    1. To inform healthcare professionals of the increased risk of drug-associated depression and suicidality, proper titration and dosing, and the risk of drug-drug interactions with strong CYP2D6 inhibitors in patients taking Xenazine.

Xiaflex

1. The goals of the XIAFLEX REMS are:
    1. To inform healthcare providers about the risks of tendon rupture, serious adverse reactions affecting the injected extremity, and the potential risk of serious hypersensitivity reactions (including the potential for anaphylaxis) associated with XIAFLEX.
    2. To inform healthcare providers about how to properly inject XIAFLEX and perform finger extension procedures.

Yervoy

1. The goal of the YERVOY REMS is to inform healthcare providers about the serious risks associated with YERVOY, including risks of severe and fatal immune-mediated adverse reactions such as fatal immune-mediated enterocolitis (including gastrointestinal perforation), fatal immune-mediated hepatitis (including hepatic failure), fatal immunemediated toxicities of skin (including toxic epidermal necrolysis), fatal nervous system toxicity, and endocrinopathies, and the management of these reactions.

Zyban

1. The goal of this REMS is to inform patients about the serious risks associated with the use of ZYBAN.

Zyprexa Relprevv

1. The goal of the Zyprexa Relprevv Patient Care Program is to mitigate the risk of negative outcomes associated with Zyprexa Relprevv post-injection delirium/sedation syndrome (PDSS) by:
    1. ensuring Zyprexa Relprevv is prescribed only by certified prescribers, dispensed only by certified dispensers, and dispensed for use only in certified healthcare facilities with ready access to emergency response services, and dispensed for use only with documentation of safe use conditions;
    2. informing healthcare providers and patients about the risks and the need for continuous observation of patients for at least 3 hours in certified health care facilities; and
    3. establishing long-term safety and safe use of Zyprexa Relprevv through periodic monitoring for the risk of PDSS events and by enrolling all patients who receive Zyprexa Relprevv in the Zyprexa Relprevv Patient Care Program Registry.