

## **Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Patient Experiences with REMS Programs**

### **Drug-Specific Content for Patient Interview Guide**

#### **1. Alemtuzumab [Lemtrada]**

Indication: Relapsing multiple sclerosis

The FDA's safety program is called Risk Evaluation and Mitigation Strategies or REMS. The purpose of a REMS program is to make sure a drug with safety concerns is used in a way that its benefits outweigh its risks. Alemtuzumab was required to have a REMS program because of an increased risk of autoimmune conditions, infusion reactions, stroke, and certain cancers. As part of the alemtuzumab REMS program, patients must have regular skin exams and laboratory tests, and agree to monitoring for side effects during treatment and for a period of time after treatment has stopped.

#### **2. Ambrisentan [Letairis]**

Indication: Pulmonary arterial hypertension

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#### **3. Bosentan [Tracleer]**

Indication: Pulmonary arterial hypertension

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#### **4. Clozapine [Versacloz/Fazaclo/Clozaril]**

Indication: Treatment-resistant schizophrenia

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**5. Isotretinoin [Accutane]**

Indication: Severe recalcitrant nodular acne

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**6. Lenalidomide [Revlimid]**

Indication: Multiple myeloma and some types of lymphoma

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**7. Pomalidomide [Pomalyst]**

Indication: Treatment-resistant multiple myeloma; AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy or in patients with Kaposi sarcoma who are HIV-negative.

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**8. Thalidomide [Thalomid]**

Indication: Multiple myeloma; erythema nodosum leprosum (ENL)

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**9. Pegvaliase-pqpz [Palynziq]**

Indication: Phenylketonuria

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**10. Sodium Oxybate [Xyrem]**

Indication: Cataplexy or excessive daytime sleepiness

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