Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer

Failure to comply with the ESA* APPRISE Oncology Program requirements will result in suspension of access to ESAs (Aranesp® and Epogen®/Procrit®) at the hospital(s) for which you are responsible.

Select a Hospital Designee

This individual is designated by hospital management to assume authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program in the hospital (eg, Pharmacy Director, Head of Hematology/Oncology Department).

Complete Training

The Hospital Designee must complete the ESA APPRISE Oncology Program training for Hospital Designees.

Enroll

The Hospital Designee must enroll in the ESA APPRISE Oncology Program by completing the ESA APPRISE Oncology Program Enrollment Form for Hospitals.

Implement

The Hospital Designee must establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that ESAs are only dispensed to patients with cancer after verifying:

- that the healthcare provider (HCP) who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is certified in the ESA APPRISE Oncology Program.
  - if an HCP who prescribes Aranesp® or Epogen®/Procrit® is not certified in the ESA APPRISE Oncology Program, the provider will be notified that he/she is not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
- that the discussion between the patient and ESA APPRISE Oncology Program-certified provider on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and provider signatures on the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) prior to initiation of each new course of Aranesp® or Epogen®/Procrit® therapy.

Please see the Aranesp®, Epogen® and Procrit® prescribing information, including Boxed WARNINGS and Medication Guides available at www.esa-apprise.com.

*ESA = erythropoiesis stimulating agent [Aranesp® (darbepoetin alfa)/Epogen® (epoetin alfa)/Procrit® (epoetin alfa)]. Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules. Aranesp® and Epogen® are registered trademarks of Amgen Inc. Procrit® is a registered trademark of Janssen Products, LP. This document has been prepared by the US Food and Drug Administration as part of a Risk Evaluation and Mitigation Strategy (REMS) for Aranesp®, Epogen® and Procrit®.

To train and enroll, contact your local Amgen or Janssen Products, LP Field Representative or access the ESA APPRISE Oncology Program Website at www.esa-apprise.com. If you are unable to enroll via a field representative or online, please call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 for further assistance.