

**ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form (Acknowledgment Form)**  
*For the use of erythropoiesis stimulating agents (ESAs\*) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer*

**Instructions for Healthcare Providers**

- Review the contents of the appropriate Medication Guide with your patient.
- Counsel your patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
- Complete each section of the form as required with your patient.

**In private-practice clinics**  
 Fax the completed form (or modified version consistent with the allowable changes) to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124 or mail a copy using the prepaid envelope to the ESA APPRISE Oncology Program Call Center at P.O. Box # 29000, Phoenix, AZ 85038. Keep a record of the signed Acknowledgment Form. The Acknowledgment Form must be available to the ESA APPRISE Oncology Program for monitoring/auditing purposes in a manner that does not require disclosure of the patient's medical record.

**In hospitals**  
 Provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

**Patient Acknowledgment of Receipt of Aranesp®, Epogen®, or Procrit® Medication Guide and ESA Risk/Benefit Discussion and Authorization for Release of this Acknowledgment Form (Required)**

Aranesp® and Epogen®/Procrit® are different drugs and your doctor will decide which one is right for you.

I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:

- I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
- I have had all my questions or concerns about Aranesp® or Epogen®/Procrit® answered by my healthcare professional.
- I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots, and I may die sooner.
- I hereby authorize my healthcare provider to release and disclose this Acknowledgment Form or a copy of this Acknowledgment Form to the Program Sponsors (Amgen and Janssen Products, LP) and their contracted data management administrator (Administrator) solely for the purpose of allowing the Program Sponsors and Administrator to monitor compliance with the Program.
- I also authorize the Sponsors and/or Administrator to contact my Healthcare Professional to collect, enter and maintain my Acknowledgment Form information in a database, and to make submissions to government agencies, including the FDA, regarding Program effectiveness, or as required by law.
- I understand that once my Acknowledgment Form information has been disclosed to the Program Sponsors and Administrator, federal privacy laws may no longer protect the information and it may be subject to re-disclosure. However, the Program Sponsors and Administrator agree to protect my information by using it and disclosing it only for the purposes described above.
- I understand that I may revoke this Authorization at any time by faxing a signed, written request to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124.
- I understand this Authorization expires ten (10) years from the date of my signature, or earlier, if required by applicable law. Further, I understand I have a right to receive a copy of this Authorization.

**Healthcare Professional Acknowledgment (Required)**

I acknowledge that prior to prescribing my patient's first dose of ESA therapy:

- I provided my patient with an ESA drug Medication Guide and instructed the patient to read it carefully before signing this form.
- I counseled my patient on the risks and benefits of ESAs, using the Medication Guide as the review tool in counseling the patient.
- I discussed all concerns and answered all questions my patient had about ESAs or his/her treatment to the best of my ability.
- The patient signed the Acknowledgment Form in my presence.

\*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 required by the US Food and Drug Administration as part of a Risk Evaluation and Mitigation Strategy (REMS) for Aranesp®, Epogen®, and Procrit®.

V4 05/12

Hospitals and prescribers in private practice clinics that are enrolled in the ESA APPRISE Oncology Program may modify the Acknowledgment Form and present the modified form to patients in either paper or electronic form, provided that the Acknowledgment Form conforms with the following criteria:

### Allowable formatting-related changes include:

- Removal of title, instructions, and footnoted text
- Addition of patient identifier and/or clinic/hospital identifiers (e.g., name and/or logo, barcodes)
- Changes to make the form compatible with existing systems, including electronic- and paper-based systems

**NO changes should be made to boxed content**

The hospital or private practice must maintain evidence of compliance that the Acknowledgment Form was signed by both the patient and the prescriber prior to the initiation of a new course of ESA therapy. Private practices must provide the completed forms to the ESA APPRISE Oncology Program Call Center.



Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs