

ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)
Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa) are Erythropoiesis Stimulating Agents (ESAs®) used for patients with cancer

Instructions for Healthcare Providers

- Counsel the 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 the patient.
- Provide a copy of the signed form to the patient.
- Make completed Acknowledgment Forms available to the ESA APPRISE Oncology Program (Program) for auditing purposes.
 - In a private practice-based clinic, store and archive the completed forms so that they are retrievable.
 - In a hospital, provide the completed forms to the Hospital Designee responsible for maintaining and storing the forms.

Patient Acknowledgment of ESA Benefits and Risks

Aranesp® and Epogen®/Procrit® are prescription medicines used to treat anemia. They are in a class of medicines called erythropoiesis stimulating agents, or ESAs. These medicines are different from each other, so your healthcare provider will decide which one is right for you.

Benefits: People with anemia have a lower-than-normal number of red blood cells (RBCs). ESAs work like the human protein called erythropoietin to help your body make more RBCs. ESAs are used to reduce or avoid the need for RBC transfusions.

Risks: ESAs may make my tumor grow faster and I may die sooner.

By signing this form, I acknowledge that my healthcare provider did the following before I received my first dose of an ESA:

- Told me about the benefits and risks of ESA therapy
- Answered all of my questions or concerns about my treatment with an ESA

Written Permission to Share Information

I permit my healthcare provider to share this form with Amgen and Janssen Products, LP (the Sponsors) and their contractors that manage certain aspects of the ESA APPRISE Oncology Program (the Contractors). The Program Sponsors and Contractors agree to keep my information secure. They will use it only to make sure Program rules are being followed.

I understand that:

- If I do not sign this form, I will not receive an ESA
- After my information has been shared with the Program Sponsors and Contractors, federal privacy laws no longer protect it. This means that the Sponsors and Contractors can give it to others, such as the Food and Drug Administration, to learn about Program effectiveness, as required by law
- I can cancel my permission at any time by providing written notice to my healthcare provider
- My permission lasts until the Program ends

Signature of patient or patient representative _____ Printed name of patient representative _____ Date (MM/DD/YY) _____

Printed patient name _____ Relationship to patient (if applicable) _____

Healthcare Provider Acknowledgment

I acknowledge that prior to the initiation of this new course of ESA therapy:

- I counseled the patient on the risks and benefits of ESAs by reviewing the Acknowledgment Form.
- I discussed all concerns and answered all questions the patient had about treatment with ESAs to the best of my ability.
- The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

Healthcare Provider Enrollment ID# _____

Signature of Healthcare Provider _____

Printed name of Healthcare Provider _____

Date (MM/DD/YY) _____ (Pre-populated information)

Site ID _____
 Site Name _____
 Site Address (Address, City, State, Zip) _____

*Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules. Or modified version consistent with the allowable changes. Aranesp® and Epogen® are registered trademarks of Amgen Inc. Procrit® is a registered trademark of Janssen Products, LP. VS 10/13

Hospitals and healthcare providers in private practice-based clinics that are certified in the ESA APPRISE Oncology Program may modify the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (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 (eg, 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-based clinic must maintain evidence of compliance that the Acknowledgment Form was signed by both the patient or patient representative and the healthcare provider prior to the initiation of each new course of ESA therapy.



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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ANN T FARRELL
12/31/2013