ESA APPRISE Oncology Program
Enrollment Form for Healthcare Providers

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer*

To become certified, healthcare providers must train and enroll into the ESA APPRISE Oncology Program:

- Complete the ESA APPRISE Oncology Program Training Module for Healthcare Providers.
- Complete this enrollment form and fax it to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124.

Failure to comply with the ESA APPRISE Oncology Program requirements will result in suspension of your access to ESAs.

By completing this form, I agree to the following:

- I have reviewed the appropriate current prescribing information for Aranesp® or Epogen®/Procrit®.
  - I understand that ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
  - I understand that ESAs increased the risk of death from cardiovascular and thromboembolic reactions in clinical studies in patients with cancer treated with ESAs.
  - I understand that in order to decrease these risks, the lowest dose of ESAs should be used to avoid red blood cell transfusions.
  - I understand that ESAs are indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
  - I understand that ESAs are not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.
  - I understand that ESAs are not indicated for use in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - I understand that ESAs are not indicated for use in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
  - I understand that ESAs have not been shown to improve quality of life, fatigue, or patient well-being.
  - I understand that ESAs should be discontinued following the completion of a chemotherapy course of treatment.
- I have reviewed the ESA APPRISE Oncology Program requirements and agree that:
  - I will discuss my patient's questions or concerns about Aranesp® or Epogen®/Procrit®.

When I prescribe and dispense an ESA to a patient with cancer in my clinic, when an ESA is dispensed for administration under my supervision to a patient with cancer in an infusion center, or when I prescribe or order an ESA for a patient with cancer in a hospital:	I will provide an Aranesp® or Epogen®/Procrit® Medication Guide to each oncology patient at the initiation of each new course of the respective ESA therapy. After initiation of treatment, and for as long as treatment continues, I will provide the appropriate Aranesp® or Epogen®/Procrit® Medication Guide to each oncology patient once a month during regular office visits—or, if regular office visits occur less frequently than once a month, at the next regularly scheduled office visit.

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- I will review the contents of the respective Medication Guide with the patient, counsel each patient on the risks (increased mortality, serious cardiovascular and thromboembolic reactions, and increased risk of tumor progression or recurrence) and benefits of Aranesp® or Epogen®/Procrit® I am prescribing to my patient before each new course of the respective ESA therapy. I will document that the discussion with each patient has occurred by signing the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form and by obtaining the patient's signature.
  - By signing the patient section of the form, the patient acknowledges the following:
    - 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® or my treatment 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.
  - By signing the HCP section of the form, as a healthcare provider enrolled in the ESA APPRISE Oncology Program, I acknowledge that prior to prescribing my patient's first dose of Aranesp® or Epogen®/Procrit® therapy:
    - I provided my patient with the appropriate Aranesp® or Epogen®/Procrit® Medication Guide and instructed the patient to read it carefully before signing this form.
    - I counseled my patient on the risks and benefits of Aranesp® or Epogen®/Procrit®, using the respective Medication Guide as the review tool in counseling the patient.
    - I discussed all concerns and answered all questions my patient had about Aranesp® or Epogen®/Procrit® or his/her treatment to the best of my ability.
    - The patient signed the Acknowledgment Form in my presence.

When I prescribe and dispense an ESA to a patient with cancer in my clinic, or an ESA is dispensed for administration under my supervision to a patient with cancer in an infusion center:	• I will send a signed copy of the ESA APPRISE Oncology Program Patient and Healthcare Professional Acknowledgment Form (or modified version consistent with the allowable changes) back to the ESA APPRISE Oncology Program Call Center and retain a copy for my records. • I agree that the ESA obtained for use in my patients with cancer will not be prescribed and dispensed by an uncertified HCP. • I will ensure the ESA that I prescribe will be dispensed under my supervision.
When I prescribe or order an ESA for a patient with cancer in a hospital:	• I will provide the completed ESA APPRISE Oncology Program Patient and Healthcare Professional Acknowledgment 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.

- I will comply with any program monitoring and auditing required to assess the effectiveness of the ESA APPRISE Oncology Program.

Full name (print) _____ Degree _____

Signature _____ Date _____

NPI # _____ and/or State license # _____ State _____

Phone _____ Fax _____ E-mail _____

My primary practice location is (select one): ❑ Private Practice–Based Clinic
❑ Hospital or outpatient facility affiliated with a hospital/institution

Practice location name _____

Practice address _____

City _____ State _____ ZIP _____

Practice contact name _____ Phone _____

Fax _____ E-mail _____

For ESA APPRISE Oncology Program Call Center use only: Site Program Code: _____

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Additional practice location (if applicable):
Select one: ❑ Private Practice–Based Clinic
❑ Hospital or outpatient facility affiliated with a hospital/institution

Practice location name ______________________

Address ______________________

City ______________ State ______________ ZIP ______________

Practice contact name ______________ Phone ______________

Fax ______________ E-mail ______________

For ESA APPRISE Oncology Program Call Center use only: Site Program Code: ______________

Additional practice location (if applicable):
Select one: ❑ Private Practice–Based Clinic
❑ Hospital or outpatient facility affiliated with a hospital/institution

Practice location name ______________________

Address ______________________

City ______________ State ______________ ZIP ______________

Practice contact name ______________ Phone ______________

Fax ______________ E-mail ______________

For ESA APPRISE Oncology Program Call Center use only: Site Program Code: ______________

Additional practice location (if applicable):
Select one: ❑ Private Practice–Based Clinic
❑ Hospital or outpatient facility affiliated with a hospital/institution

Practice location name ______________________

Address ______________________

City ______________ State ______________ ZIP ______________

Practice contact name ______________ Phone ______________

Fax ______________ E-mail ______________

For ESA APPRISE Oncology Program Call Center use only: Site Program Code: ______________

If you have more than 4 practice locations, please call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089.

You will receive an ESA APPRISE Oncology Program enrollment confirmation and an identification number via e-mail (or by fax if no e-mail address is provided) within 1 business day of receipt of this completed form. Within 5 business days of enrollment confirmation, an HCP Program Starter Kit including ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms and ESA Medication Guides will be shipped to each private practice location listed above. Your enrollment identification number will be required on every patient acknowledgment form.

For questions regarding the ESA APPRISE Oncology Program, please visit the ESA APPRISE Oncology Program website at **www.esa-apprise.com**, contact your local Amgen or Janssen Products, LP Field Representative, or call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089.

*ESA=erythropoiesis stimulating agent (ESA; Aranesp®/Epogen®/Procrit®).
Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

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®.

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