

**Aranesp®** (*darbepoetin alfa*), **Epogen®** (*epoetin alfa*), and **Procrit®** (*epoetin alfa*) are Erythropoiesis Stimulating Agents (ESAs) used for patients with cancer

To become certified, healthcare providers (HCPs) 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 in order to decrease these risks, the lowest dose of ESAs should be used to avoid red blood cell (RBC) 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.
- 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®.
  - I will counsel each patient on the risks (increased risk of mortality and increased risk of tumor progression or recurrence) of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy by reviewing the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form).
  - I will document that the discussion with each patient has occurred by completing an Acknowledgment Form with each patient and providing each patient a copy of the signed form.
- By signing the patient section of the form, the patient acknowledges the following:
  - I acknowledge that my healthcare provider did the following before I received my first dose of Aranesp® or Epogen®/Procrit®:
    - Told me about the benefits and risks of ESA therapy.
    - Answered all of my questions or concerns about my treatment with an ESA.
- By signing the HCP section of the form, as a healthcare provider certified in the ESA APPRISE Oncology Program, I acknowledge that prior to the initiation of each new course of ESA therapy:
  - I counseled the patient on the risks of Aranesp® or Epogen®/Procrit® by reviewing the Acknowledgment Form.
  - I discussed all concerns and answered all questions the patient had about treatment with Aranesp® or Epogen®/Procrit® 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.

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| <p><i>When I prescribe or 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, such as an infusion center:</i></p> | <ul style="list-style-type: none"> <li>I will make completed Acknowledgment Forms (or modified versions consistent with the allowable changes) available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record, and to store the Acknowledgment Forms on-site and/or archive them in a retrievable manner.</li> <li>I agree that the ESA obtained for use in my patients with cancer will not be prescribed, or prescribed and dispensed, by an uncertified HCP.</li> <li>I will ensure the ESA that I prescribe will be dispensed under my supervision.</li> </ul> |
| <p><i>When I prescribe or order an ESA therapy for a patient with cancer in a hospital:</i></p>   | <ul style="list-style-type: none"> <li>I will provide the completed Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms.</li> </ul>   |
| <ul style="list-style-type: none"> <li>I will comply with any Program auditing required to assess the effectiveness of the ESA APPRISE Oncology Program.</li> </ul>   |  |

Full name (print) \_\_\_\_\_ Degree \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

NPI # \_\_\_\_\_ and/or State license # \_\_\_\_\_ State \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ Email \_\_\_\_\_

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 \_\_\_\_\_ Email \_\_\_\_\_

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 \_\_\_\_\_ Email \_\_\_\_\_

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 \_\_\_\_\_ Email \_\_\_\_\_

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 \_\_\_\_\_ Email \_\_\_\_\_

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 email (or by fax if no email address is provided) within 1 business day of receipt of this completed form. Within 7 business days of enrollment confirmation, ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms and Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics will be shipped to each private practice location listed above. Your enrollment identification number will be required on every Acknowledgment Form.

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

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®.