



**Aranesp**<sup>®</sup>  
(darbepoetin alfa)

**EPOGEN**<sup>®</sup>  
(EPOETIN ALFA)  
RECOMBINANT

**PROCRIT**<sup>®</sup>  
EPOETIN ALFA

**AMGEN**  
Oncology



Assisting **P**roviders and cancer **P**atients with  
**R**isk Information for the **S**afe use of **ESA**s

# Training Module for Healthcare Providers

# Training Module for Healthcare Providers

Erythropoiesis Stimulating Agents (ESAs) are used to treat anemia for patients with cancer where anemia is due to the effect of concomitant myelosuppressive chemotherapy and include Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa). The Food and Drug Administration (FDA) has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for ESAs used to treat patients with cancer to ensure that the benefits of these drugs outweigh the risks of shortened overall survival and/or increased risk of tumor progression or recurrence as shown in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

The ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program is part of the REMS. This training module is required for certification in the ESA APPRISE Oncology Program and is intended for healthcare providers (HCPs) who prescribe, or prescribe and dispense, ESAs for patients with cancer.

**The goal of the REMS for Aranesp® and Epogen®/Procrit® is:**

To support informed discussions between patients with cancer and their healthcare providers by:

- educating healthcare providers about the risks and safe use conditions of ESAs for patients with cancer.
- informing patients about the risk of shortened overall survival and/or increased risk of tumor progression or recurrence when ESAs are used to treat anemia due to concomitant myelosuppressive chemotherapy.

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

This training module, as a component of this REMS Program, presents the requirements for HCPs who prescribe, or prescribe and dispense, Aranesp®, Epogen®, or Procrit® for patients with cancer.

Aranesp® and Epogen® are registered trademarks of Amgen Inc. Procrit® is a registered trademark of Janssen Products, LP.

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

Reference ID: 3429792 (REMS) for Aranesp®, Epogen®, and Procrit®.

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

# Training Module for Healthcare Providers

This Training Module features four sections:

**Section 1: Key safety information for the use of ESAs for patients with cancer**

**Section 2: Appropriate use of ESAs for patients with cancer**

**Section 3: HCP Program requirements and materials**

**Section 4: Enrollment**

Please see the Aranesp®, Epogen®, and Procrit® prescribing information, including **Boxed WARNINGS** and Medication Guides available at [www.esa-apprise.com](http://www.esa-apprise.com).

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Assisting Providers and cancer Patients with  
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# SECTION 1

## KEY SAFETY INFORMATION FOR USE OF ESAs FOR PATIENTS WITH CANCER



Assisting Providers and cancer Patients with  
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# Section 1

## Key Safety Information for Use of ESAs for Patients With Cancer

ESAs resulted in decreased locoregional control/progression-free survival and/or overall survival.

As shown in the table below, these findings were observed in studies of patients with advanced head and neck cancer receiving radiation therapy (Studies 5 and 6), in patients receiving chemotherapy for metastatic breast cancer (Study 1) or lymphoid malignancy (Study 2), and in patients with non-small cell lung cancer or various malignancies who were not receiving chemotherapy or radiotherapy (Studies 7 and 8).

Study/Tumor/(n)	Hemoglobin Target	Hemoglobin (Median; Q1, Q3*)	Primary Efficacy Outcome	Adverse Outcome for ESA-Containing Arm
<b>Chemotherapy</b>				
<b>Study 1</b> Metastatic breast cancer (n = 939)	12–14 g/dL	12.9 g/dL; 12.2, 13.3 g/dL	12-month overall survival	Decreased 12-month survival
<b>Study 2</b> Lymphoid malignancy (n = 344)	13–15 g/dL (M) 13–14 g/dL (F)	11 g/dL; 9.8, 12.1 g/dL	Proportion of patients achieving a hemoglobin response	Decreased overall survival
<b>Study 3</b> Early breast cancer (n = 733)	12.5–13 g/dL	13.1 g/dL; 12.5, 13.7 g/dL	Relapse-free and overall survival	Decreased 3-year relapse-free and overall survival
<b>Study 4</b> Cervical cancer (n = 114)	12–14 g/dL	12.7 g/dL; 12.1, 13.3 g/dL	Progression-free and overall survival and locoregional control	Decreased 3-year progression-free and overall survival and locoregional control
<b>Radiotherapy Alone</b>				
<b>Study 5</b> Head and neck cancer (n = 351)	≥ 15 g/dL (M) ≥ 14 g/dL (F)	Not available	Locoregional progression-free survival	Decreased 5-year locoregional progression-free and overall survival
<b>Study 6</b> Head and neck cancer (n = 522)	14–15.5 g/dL	Not available	Locoregional disease control	Decreased locoregional disease control
<b>No Chemotherapy or Radiotherapy</b>				
<b>Study 7</b> Non-small cell lung cancer (n = 70)	12–14 g/dL	Not available	Quality of life	Decreased overall survival
<b>Study 8</b> Non-myeloid malignancy (n = 989)	12–13 g/dL	10.6 g/dL; 9.4, 11.8 g/dL	RBC transfusions	Decreased overall survival

\*Q1 = 25th percentile Q3 = 75th percentile

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# Section 1

## Key Safety Information for Use of ESAs for Patients With Cancer

### Decreased Overall Survival

Study 1 was a randomized, placebo-controlled study of 939 women with metastatic breast cancer receiving chemotherapy; patients received either weekly epoetin alfa or placebo for up to a year. This study was designed to show that survival was superior when epoetin alfa was administered to prevent anemia (maintain hemoglobin levels between 12 and 14 g/dL or hematocrit between 36% and 42%). This study was terminated prematurely when interim results demonstrated a higher mortality at 4 months (8.7% vs. 3.4%) and a higher rate of fatal thrombotic reactions (1.1% vs. 0.2%) in the first 4 months of the study among patients treated with epoetin alfa. The most common investigator-attributed cause of death within the first 4 months was disease progression; 28 of 41 deaths in the epoetin alfa arm and 13 of 16 deaths in the placebo arm were attributed to disease progression. Investigator-assessed time to tumor progression was not different between the 2 groups. Survival at 12 months was significantly lower in the epoetin alfa arm (70% vs. 76%, HR 1.37, 95% CI: 1.07, 1.75;  $p = 0.012$ ).

Study 2 was a randomized, double-blind study (darbepoetin alfa vs. placebo) conducted in 344 anemic patients with lymphoid malignancy receiving chemotherapy. With a median follow-up of 29 months, overall mortality rates were significantly higher among patients randomized to darbepoetin alfa as compared to placebo (HR 1.36, 95% CI: 1.02, 1.82).

Study 7 was a multicenter, randomized, double-blind study (epoetin alfa vs. placebo) in which patients with advanced non-small cell lung cancer receiving only palliative radiotherapy or no active therapy were treated with epoetin alfa to achieve and maintain hemoglobin levels between 12 and 14 g/dL. Following an interim analysis of 70 patients (planned accrual 300 patients), a significant difference in survival in favor of the patients in the placebo arm of the study was observed (median survival 63 vs. 129 days; HR 1.84;  $p = 0.04$ ).

Study 8 was a randomized, double-blind study (darbepoetin alfa vs. placebo) in 989 anemic patients with active malignant disease, neither receiving nor planning to receive chemotherapy or radiation therapy. There was no evidence of a statistically significant reduction in proportion of patients receiving RBC transfusions. The median survival was shorter in the darbepoetin alfa treatment group than in the placebo group (8 months vs. 10.8 months; HR 1.30, 95% CI: 1.07, 1.57).

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# Section 1

## Key Safety Information for Use of ESAs for Patients With Cancer

### Decreased Progression-free Survival and Overall Survival

Study 3 was a randomized, open-label, controlled, factorial design study in which darbepoetin alfa was administered to prevent anemia in 733 women receiving neo-adjuvant breast cancer treatment. A final analysis was performed after a median follow-up of approximately 3 years. The 3-year survival rate was lower (86% vs. 90%; HR 1.42, 95% CI: 0.93, 2.18) and the 3-year relapse-free survival rate was lower (72% vs. 78%; HR 1.33, 95% CI: 0.99, 1.79) in the darbepoetin alfa-treated arm compared to the control arm.

Study 4 was a randomized, open-label, controlled study that enrolled 114 of a planned 460 cervical cancer patients receiving chemotherapy and radiotherapy. Patients were randomized to receive epoetin alfa to maintain hemoglobin between 12 and 14 g/dL or to RBC transfusion support as needed. The study was terminated prematurely due to an increase in thromboembolic adverse reactions in epoetin alfa-treated patients compared to control (19% vs. 9%). Both local recurrence (21% vs. 20%) and distant recurrence (12% vs. 7%) were more frequent in epoetin alfa-treated patients compared to control. Progression-free survival at 3 years was lower in the epoetin alfa-treated group compared to control (59% vs. 62%; HR 1.06, 95% CI: 0.58, 1.91). Overall survival at 3 years was lower in the epoetin alfa-treated group compared to control (61% vs. 71%; HR 1.28, 95% CI: 0.68, 2.42).

Study 5 was a randomized, placebo-controlled study in 351 head and neck cancer patients where epoetin beta or placebo was administered to achieve target hemoglobins  $\geq 14$  and  $\geq 15$  g/dL for women and men, respectively. Locoregional progression-free survival was significantly shorter in patients receiving epoetin beta (HR 1.62, 95% CI: 1.22, 2.14;  $p = 0.0008$ ) with medians of 406 days and 745 days in the epoetin beta and placebo arms respectively. Overall survival was significantly shorter in patients receiving epoetin beta (HR 1.39, 95% CI: 1.05, 1.84;  $p = 0.02$ ).

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# Section 1

## Key Safety Information for Use of ESAs for Patients With Cancer

### Decreased Locoregional Control

Study 6 was a randomized, open-label, controlled study conducted in 522 patients with primary squamous cell carcinoma of the head and neck receiving radiation therapy alone (no chemotherapy) who were randomized to receive darbepoetin alfa to maintain hemoglobin levels of 14 to 15.5 g/dL or no darbepoetin alfa. An interim analysis performed on 484 patients demonstrated that locoregional control at 5 years was significantly shorter in patients receiving darbepoetin alfa (RR 1.44, 95% CI: 1.06, 1.96;  $p = 0.02$ ). Overall survival was shorter in patients receiving darbepoetin alfa (RR 1.28, 95% CI: 0.98, 1.68;  $p = 0.08$ ).

Please see the full prescribing information for Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) for other risks associated with these ESAs, including other Warnings and Precautions, and Adverse Reactions.

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# SECTION 2

## APPROPRIATE USE OF ESAs FOR PATIENTS WITH CANCER

# Section 2

## Appropriate Use of ESAs for Patients With Cancer

- 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.
- ESAs are not indicated for use:
  - in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
  - as a substitute for RBC transfusions in patients who require immediate correction of anemia.
- ESAs have not been shown to improve quality of life, fatigue, or patient well-being.

### Important Dosing and Treatment Information

- Initiate ESAs in patients on cancer chemotherapy only if the hemoglobin is less than 10 g/dL.
- Use the lowest dose of ESAs necessary to avoid RBC transfusions.
- Discontinue ESAs following the completion of a chemotherapy course.

Please see the Aranesp®, Epogen® and Procrit® prescribing information, including **Boxed WARNINGS** and Medication Guides available at [www.esa-apprise.com](http://www.esa-apprise.com).

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## Section 2

# Healthcare Provider Knowledge Check

Answer true or false to the following statements:

**1** **True or False:** ESAs are not indicated for the treatment of anemia in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.

**2** **True or False:** Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy only when hemoglobin level is less than 11 g/dL.

**3** **True or False:** ESAs should be discontinued following the completion of a chemotherapy course.

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## Section 2

# Answers to the Healthcare Provider Knowledge Check

**1 TRUE** The correct statement is: ESAs are not indicated for the treatment of anemia in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.

**2 FALSE** The correct statement is: Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy only when hemoglobin level is less than 10 g/dL.

**3 TRUE** The correct statement is: ESAs should be discontinued following the completion of a chemotherapy course.

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SECTION 3  
PROGRAM REQUIREMENTS  
AND MATERIALS FOR  
HEALTHCARE PROVIDERS



# Section 3

## Program Requirements and Materials for Healthcare Providers

- To learn more about allowable changes to the Acknowledgment Form, please refer to the Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics flashcard accessible at [www.esa-apprise.com](http://www.esa-apprise.com) in the Forms & Resources section.

**Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics**

**ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)**

**Instructions for Healthcare Providers**

1. Counsel the patient on the risks and benefits of Aranesp® and Epogen®/Procrit® before each new course of ESA.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient.
4. Note: completed Acknowledgment Form available to the ESA APPRISE Oncology Program (Program) for auditing.
5. In a private practice-based clinic, store and archive the completed forms as described in the instructions.
6. In a hospital, provide the completed forms to the Hospital Designated responsible for maintaining and storing the forms.

**Written Permission to Share Information**

**Healthcare Provider Acknowledgment**

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

**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

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.

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

## Section 3

# Program Requirements and Materials for Healthcare Providers

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

Upon completion of this enrollment process, you will receive an ESA APPRISE Oncology Program enrollment identification (ID) number via email (or by fax if no email address is provided). Your enrollment ID number will be required on every Acknowledgment Form.

Once you have enrolled, you will receive materials to assist you in implementing the ESA APPRISE Oncology Program. These materials will be shipped to each private practice location listed on your enrollment form. If your primary practice location is a hospital, these materials will be sent to the Hospital Designee.

### These materials include:

- ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms
- Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics
- Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer

Should you have any questions during this training and enrollment process, call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 or contact your local Amgen or Janssen Products, LP Field Representative.

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# SECTION 4

## HEALTHCARE PROVIDER ENROLLMENT



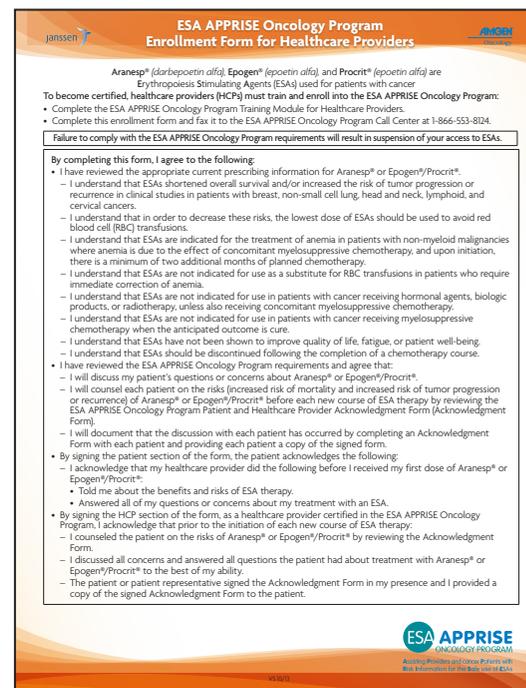
Assisting Providers and cancer Patients with  
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# Section 4

## Healthcare Provider Enrollment

Now that you have completed the ESA APPRISE Oncology Program Training Module, you are ready to enroll. Enrollment confirms the fact that you have reviewed the safety and appropriate use information for ESAs for patients with cancer, commits you to complying with the Program requirements, and asks you to list all your sites of practice.

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



The image shows a sample of the "ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers". The form is titled "ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers" and includes the Janssen and Amgen logos. It contains the following text:

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.

At the bottom right of the form is the "ESA APPRISE ONCOLOGY PROGRAM" logo with the tagline "Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs".

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