

**Initial REMS Approval: 02/2010**

**Most Recent Modification: 12/2013**

**BL 103951 ARANESP® (DARBEPOETIN ALFA)**

Amgen Inc.

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**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOAL**

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

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

**II. REMS ELEMENTS**

**A. Elements to Assure Safe Use**

**1. Healthcare providers (HCPs) who both prescribe<sup>1</sup> and dispense<sup>2</sup> Aranesp for patients with cancer in private practice settings and healthcare providers who prescribe Aranesp for patients with cancer in hospitals are specially certified.**

- a. Amgen will ensure that HCPs who both prescribe and dispense Aranesp for patients with cancer in private practice settings and HCPs who prescribe Aranesp for patients with cancer in hospitals are certified.

To become specially certified, each HCP must enroll in the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs {erythropoiesis stimulating agents}) Oncology Program by doing the following:

- i. Review the prescribing information.

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<sup>1</sup> For the purposes of this REMS, the terms prescribe and prescription include medication orders in the clinic or hospital settings.

<sup>2</sup> For the purposes of this REMS, dispense in a private practice setting includes dispensing for administration in a provider's office or under the supervision of a provider, such as in an infusion center.

- ii. Complete the ESA APPRISE Oncology Program Training Module for Healthcare Providers.
- iii. Complete and sign the ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers and submit it to the ESA APPRISE Oncology Program Call Center.
- iv. Agree to counsel each patient on the risks of ESAs by reviewing and signing the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) (or modified version consistent with the allowable changes) and to provide a copy of the signed Acknowledgment Form to the patient.
  - 1) HCPs in a private clinic practice setting agree to maintain a completed Acknowledgment Form for auditing purposes in a manner that does not require the disclosure of the patient's medical record, and to store the Acknowledgment Forms on-site and/or archive them in a retrievable manner.
  - 2) HCPs in a hospital setting agree to provide the completed Acknowledgment Forms to the Hospital Designee responsible for maintaining and storing the forms on-site and/or archiving them in a retrievable manner.

b. Amgen will:

- i. Send a DHCP Letter to non-certified HCPs who may prescribe, or prescribe and dispense, Aranesp for patients with cancer instructing them how to become certified in the ESA APPRISE Oncology Program.
- ii. Provide each certified HCP a unique ESA APPRISE Oncology Program enrollment identification (ID) number, which will be used to confirm certification in the Program.
- iii. Maintain a secure and accurate database of HCPs certified in the ESA APPRISE Oncology Program.
- iv. Ensure that, as part of the enrollment process, HCPs receive the following materials that are part of the ESA APPRISE Oncology Program:
  - 1) Dear Healthcare Provider (DHCP) Letter to Newly Identified HCPs who may Prescribe, or Prescribe and Dispense, ESAs for Patients with Cancer
  - 2) ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers
  - 3) ESA APPRISE Oncology Program Training Module for Healthcare Providers
  - 4) Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer

- 5) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form
- 6) Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics
- v. Inform certified HCPs following important modifications to the Aranesp REMS or to the ESA APPRISE Oncology Program
- vi. Ensure that ESA APPRISE Oncology Program materials are available on the Program website or can be obtained by contacting the ESA APPRISE Oncology Program Call Center at 1-866-284-8089.

The following materials are part of the REMS and are appended:

- Dear Healthcare Provider (DHCP) Letter to Newly Identified HCPs who may Prescribe, or Prescribe and Dispense, ESAs for Patients with Cancer
- ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers
- ESA APPRISE Oncology Program Training Module for Healthcare Providers
- Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer
- ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form
- ESA APPRISE Oncology Program Website

**2. Hospitals that dispense Aranesp for patients with cancer are specially certified.**

- a. Amgen will ensure that hospitals that dispense Aranesp are certified in the ESA APPRISE Oncology Program.

To become specially certified, a Hospital Designee (eg, Pharmacy Director, Head of Hematology/Oncology, or other appointed designee) must enroll into the ESA APPRISE Oncology Program by doing the following:

- i. Complete the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- ii. Agree to assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in hospital(s) for which they are responsible.
- iii. Agree to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the ESA APPRISE Oncology Program, such that:
  - 1) Aranesp is only dispensed to patients with cancer after verifying:

- a) that the healthcare provider who prescribed Aranesp for patients with cancer is certified in the ESA APPRISE Oncology Program; and
  - b) the discussion between the patient and ESA APPRISE Oncology Program-certified provider on the risks of Aranesp therapy is documented by patient and provider signatures on the Acknowledgment Form (or modified version consistent with the allowable changes) prior to initiation of each new course of Aranesp therapy.
- 2) If an HCP that prescribes Aranesp is not certified in the ESA APPRISE Oncology Program, the provider will be notified that they are not able to prescribe Aranesp for patients with cancer.
- iv. Oversee compliance with program auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
- v. Maintain evidence of compliance with the ESA APPRISE Oncology Program for auditing purposes, as follows:
- 1) documentation (ie, unique enrollment ID number) that each HCP in the hospital who prescribes Aranesp for patients with cancer is certified in the ESA APPRISE Oncology Program
  - 2) documentation of the risk:benefit discussion between certified provider and patient on the Acknowledgment Form (or modified version consistent with the allowable changes) for each patient with cancer for whom an Aranesp prescription was filled; the Acknowledgment Forms are to be stored on-site and/or archived in a retrievable manner.
- vi. Complete and sign the ESA APPRISE Oncology Program Enrollment Form for Hospitals and submit it to the ESA APPRISE Oncology Program Call Center.
- b. Amgen will:
- i. Send a Dear Director of Pharmacy/Administrator Letter to non-certified hospitals that dispense Aranesp for patients with cancer, instructing them how to become certified in the ESA APPRISE Oncology Program.
  - ii. Provide each hospital with a unique ESA APPRISE Oncology Program enrollment ID number that will be used to confirm certification in the Program.
  - iii. Ensure that the ESA APPRISE Oncology Program Call Center maintains a secure and accurate database of certified hospitals in the ESA APPRISE Oncology Program.



- iv. Ensure that, as part of the enrollment process, the Hospital Designee receives the following materials that are part of the ESA APPRISE Oncology Program:
  - 1) Dear Healthcare Provider (DHCP) Letter to Directors of Pharmacy/Administrators of Newly Identified Hospitals That Dispense ESAs to Patients With Cancer
  - 2) ESA APPRISE Oncology Program Enrollment Form for Hospitals
  - 3) ESA APPRISE Oncology Program Training Module for Hospital Designees
  - 4) Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer
  - 5) Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer
  - 6) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form
  - 7) Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics
- v. Inform certified Hospital Designees following important modifications to the Aranesp REMS or to the ESA APPRISE Oncology Program.
- vi. Ensure that ESA APPRISE Oncology Program materials are available on the Program website or can be obtained by contacting the ESA APPRISE Oncology Program Call Center at 1-866-284-8089.

The following materials are part of the REMS and are appended:

- Dear Healthcare Provider (DHCP) Letter to Directors of Pharmacy/Administrators of Newly Identified Hospitals That Dispense ESAs to Patients With Cancer
- ESA APPRISE Oncology Program Enrollment Form for Hospitals
- ESA APPRISE Oncology Program Training Module for Hospital Designees
- Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer

**3. Aranesp will be dispensed to patients with cancer with evidence or other documentation of safe-use conditions.**

Amgen will ensure that certified hospitals and certified HCPs agree to only dispense Aranesp to patients with cancer once the risk:benefit discussion has occurred and patients and their certified HCPs have signed the Acknowledgment Form (or modified version consistent with the allowable changes) prior to the initiation of each new course of ESA therapy.

## **B. Implementation System**

The Implementation System includes the following:

1. Amgen will monitor compliance with completion of the Acknowledgment Form (or modified version consistent with the allowable changes) and will work to improve implementation if non-compliance is identified.
  - a. Amgen will allow certain changes to the Acknowledgment Form to ensure that the form can be adapted by hospitals and private practices to be compatible with their existing systems. The allowable formatting-related changes are:
    - i. Removal of title instruction and footnoted text
    - ii. Addition of patient identifier and/or clinic/hospital identifiers (eg, name and/or logo, barcodes)
    - iii. Changes to make the form compatible with existing systems, including electronic- and paper-based systems

The content in the Patient and HCP sections of the Acknowledgment Form cannot be changed. No content can be added or removed from these sections.

The Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics is part of the REMS and is appended.

- b. The ESA APPRISE Oncology Program will audit selected private practice-based clinics. For each audit, a sample of at least 100 clinics that have purchased ESAs during the audit period that were not included in the prior audit will be selected. Each audit will be conducted according to a time schedule that allows these data to be provided with each REMS assessment. HCPs in private practice-based clinics will be audited by the ESA APPRISE Oncology Program to demonstrate evidence of compliance with the Program as follows:
  - i. That the number of HCPs who prescribe ESAs for patients with cancer in the private practice-based clinic is not greater than the number of HCPs in the private practice-based setting that are certified in the ESA APPRISE Oncology Program (by unique ESA APPRISE Oncology Program enrollment ID number).
  - ii. That the number of patient- and HCP-signed Acknowledgment Forms retained at the clinic is not less than the number of patients with cancer initiating a new course of ESA therapy.
- c. For hospitals, the ESA APPRISE Oncology Program will identify at least 25 hospitals with ESA use in patients with cancer during the audit period. The audits will be conducted according to a time schedule that allows these data to be provided with each REMS assessment. These hospitals will be audited by the ESA APPRISE Oncology Program to demonstrate evidence of compliance with the Program as follows:

- i. That the documentation maintained by hospitals demonstrates that each HCP in the hospitals who prescribe ESAs for patients with cancer is certified in the ESA APPRISE Oncology Program (by unique ESA APPRISE Oncology Program enrollment ID number).
  - ii. That the number of patient- and HCP-signed Acknowledgment Forms retained at the hospital is not less than the number of patients with cancer initiating a new course of ESA therapy. For the audits to be effective, hospitals will implement a means to determine the total number of individual patients that received Aranesp based on orders and prescriptions written.
2. For sites that are non-compliant, Amgen will request that the non-compliant clinic or hospital develop, submit, and implement a plan to correct findings. The site will automatically be included in a for-cause audit for the subsequent audit cycle. If continued non-compliance is identified, the HCP or hospital will have their access to ESAs suspended. Removal from the Suspended Access List will require correction of non-compliance with the REMS requirements.
3. Amgen will instruct distributors not to ship an ESA to a hospital or HCP at a private practice-based clinic without confirmation from the ESA APPRISE Oncology Program Call Center that the hospital or the HCP is certified or that certification is not applicable (ie, the hospital does not dispense an ESA for patients with cancer or the HCP does not prescribe, or prescribe and dispense, an ESA for patients with cancer in a private practice-based clinic).
4. Amgen will monitor HCP and hospital certification on an ongoing basis to evaluate compliance with the ESA APPRISE Oncology Program certification requirements and will work to improve implementation of this element.
5. If there are important modifications to the Aranesp REMS and to the ESA APPRISE Oncology Program, Amgen will update all affected materials and notify certified HCPs and hospitals, as applicable.

Based on monitoring and evaluation of these elements to assure safe use, Amgen will take reasonable steps to improve implementation of these elements.

### **C. Timetable for Submission of Assessments of the REMS**

Amgen will submit REMS Assessments at 8 months, 1 year, 18 months, 24 months, and annually thereafter following the initial approval (02/2010) of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Amgen will submit each assessment so that it will be received by the FDA on or before the due date.

Name  
Address  
City, State Zip

[Date]

Re: ACTION REQUIRED for Healthcare Providers (HCPs) who Prescribe ESAs (erythropoiesis stimulating agents) for Patients With Cancer

Dear [Insert First Name] [Insert Last Name],

Our records indicate that you have recently been identified as an HCP at [Insert Clinic Name] and you may prescribe, or prescribe and dispense, ESAs to patients with cancer. In order to continue to obtain ESAs for patients with cancer, you must train and enroll in the ESA APPRISE Oncology Program no later than [insert 90 day enrollment date] or your access to ESAs will be suspended. You can take the training and enroll in the Program at [www.esa-apprise.com](http://www.esa-apprise.com).

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for ESAs 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 you may be aware, on 16 February 2010, the FDA approved a REMS for ESAs (Aranesp®, Epogen®/Procrit®) used to treat patients with cancer.

The ESA APPRISE Oncology Program applies to HCPs who prescribe, or prescribe and dispense, and hospitals that dispense ESAs to patients with cancer. One of the key requirements of the ESA APPRISE Oncology Program is that any HCP who prescribes, or prescribes and dispenses, ESAs for patients with cancer must train and enroll in the Program.

If our records are not accurate or if you have any questions regarding this letter, please contact your local Amgen or Janssen Products, LP Field Representative or call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 as soon as possible.

For oncology, 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.

For oncology, ESAs are not indicated for use:

- As a substitute for RBC transfusions in patients who require immediate correction of anemia.
- 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.

ESAs have not been shown to improve quality of life, fatigue, or patient well-being.

Although the ESA APPRISE Oncology Program applies to both Aranesp® and Epogen®/Procrit®, these are different drugs with distinct dosing schedules.

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

Sincerely,

Amgen  
Janssen Products, LP

Enclosures:  
Aranesp®, Epogen®, and Procrit® Prescribing Information and Medication Guides

Name  
Address  
City, State Zip  
[Date]

Re: ACTION REQUIRED for Hospitals That Dispense ESAs (erythropoiesis stimulating agents) for Patients With Cancer  
Dear Hospital Administrator/Director of Pharmacy,

Our records indicate your hospital [Insert Hospital name] has recently been identified as a hospital dispensing ESAs on behalf of healthcare providers (HCPs) treating patients with an ESA for their cancer. In order to continue to obtain ESAs for patients with cancer, your hospital must designate a representative (eg, Pharmacy Director or Head of Hematology/Oncology) who, as the Hospital Designee, must train and enroll in the ESA APPRISE Oncology Program by [insert 90 day enrollment date] or your hospital's access to ESAs will be suspended. The Hospital Designee can take the training and enroll in the Program at [www.esa-appraise.com](http://www.esa-appraise.com).

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for ESAs 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 you may be aware, on 16 February 2010, the FDA approved a REMS for ESAs (Aranesp®, Epogen®/Procrit®) used to treat patients with cancer.

The ESA APPRISE Oncology Program applies to HCPs who prescribe, or prescribe and dispense, and hospitals that dispense ESAs to patients with cancer. One of the key requirements of the ESA APPRISE Oncology Program is that any hospital that dispenses ESAs on behalf of HCPs treating patients with an ESA for their cancer must enroll in and comply with the Program.

If our records are not accurate or if you have any questions regarding this letter, please contact your local Amgen or Janssen Products, LP Field Representative or call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 as soon as possible.

For oncology, 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.

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Although the ESA APPRISE Oncology Program applies to both Aranesp® and Epogen®/Procrit®, these are different drugs with distinct dosing schedules.

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

Sincerely,

Amgen  
Janssen Products, LP

Enclosures:  
Aranesp®, Epogen®, and Procrit® Prescribing Information and Medication Guides

**ESA APPRISE Oncology Program Web Site**

# **Site Screenshots**

**September 5, 2013**

**Version 4.0.10**

*FDA Updates*

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**Recent Program Modifications**

**Key Highlights**

- The requirement for a healthcare provider (HCP) in a private practice-based clinic to mail or fax a copy of the Acknowledgment Form to the Program Call Center has been eliminated
- A copy of the signed Acknowledgment Form must be provided to each patient
- The Acknowledgment Form has been revised. Replace all unused versions of the Acknowledgment Form with version 5 10/13
- The ESA APPRISE Oncology Program no longer requires re-enrollment for Healthcare Providers or Hospital Designees

**Please click on "Recent Program Modifications" to view a complete list of changes and updates.**

**What is Erythropoiesis-Stimulating Agent (ESA) Therapy?**

Erythropoiesis-Stimulating Agent (ESA) therapy is used to treat anemia in patients with cancer and to improve quality of life.

Amgen and Janssen Products, LP provide ESAs to healthcare providers and cancer patients.

**What are the risks of ESAs?**

- In clinical studies, 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.

**Key Program Requirements**

Healthcare Providers	Hospitals
<b>1. Complete Training</b>	<b>1a. Select a Hospital Designee</b> <b>1b. Hospital Designee Completes Training</b>
<b>2. Enroll in the ESA APPRISE Oncology Program</b>	<b>2. Enroll in the ESA APPRISE Oncology Program</b>
<b>3. Counsel and Document</b> <ul style="list-style-type: none"> <li>• Counsel each patient on the risks of ESAs prior to each new course of ESA therapy.</li> <li>• Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form and providing each patient a copy of the signed form.</li> </ul>	<b>3. Implement</b> <ul style="list-style-type: none"> <li>• Hospital Designee to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program.</li> </ul>

The [ESA APPRISE Oncology Program training and enrollment](#) takes you step-by-step through the required training and enrollment process.

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

**Questions about the ESA APPRISE Oncology Program?**

If you need more information about the ESA APPRISE Oncology Program:

- Call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089, or
- Contact your local Amgen or Janssen Products, LP Field Representative

\*Additional information on REMS may be found at [www.FDA.gov](http://www.FDA.gov)

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®.



## Welcome to the ESA APPRISE Oncology Program

Train and enroll



Learn more



Access forms & resources



Recent Program Modifications

### What is the ESA APPRISE Oncology Program?

Erythropoiesis Stimulating Agents (ESAs) include Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa). The Food and Drug Administration (FDA) determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the decision to initiate ESA treatment for a patient with cancer begins with a discussion between the patient and healthcare provider (HCP) about the benefits and risks associated with ESA therapy.\*

Amgen and Janssen Products, LP have implemented the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program as part of a REMS designed for HCPs treating patients with an ESA for their cancer.

### What are the risks addressed through the ESA APPRISE Oncology Program?

- **Increased risk of death and/or increased risk of tumor progression or recurrence in patients with cancer.**
  - 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.

### Key Program Requirements

Healthcare Providers	Hospitals
<b>1. Complete Training</b>	<b>1a. Select a Hospital Designee</b> <b>1b. Hospital Designee Completes Training</b>
<b>2. Enroll in the ESA APPRISE Oncology Program</b>	<b>2. Enroll in the ESA APPRISE Oncology Program</b>
<b>3. Counsel and Document</b> <ul style="list-style-type: none"> <li>• Counsel each patient on the risks of ESAs prior to each new course of ESA therapy.</li> <li>• Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form and providing each patient a copy of the signed form.</li> </ul>	<b>3. Implement</b> <ul style="list-style-type: none"> <li>• Hospital Designee to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program.</li> </ul>

[The ESA APPRISE Oncology Program training and enrollment](#) takes you step-by-step through the required training and enrollment process.

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

### Questions about the ESA APPRISE Oncology Program?

If you need more information about the ESA APPRISE Oncology Program:

- Call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089, or
- Contact your local Amgen or Janssen Products, LP Field Representative

\*Additional information on REMS may be found at [www.FDA.gov](http://www.FDA.gov)

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## Recent Program Modifications

- **The goal of the REMS has been changed to focus on the risks of using ESAs for patients with cancer:**  
The goal of the REMS 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 Aranesp<sup>®</sup> (darbepoetin alfa) and Epogen<sup>®</sup>/Procrit<sup>®</sup> (epoetin alfa) for patients with cancer.
  - informing patients about the risks of shortened overall survival and/or increased risk of tumor progression or recurrence when Aranesp<sup>®</sup> or Epogen<sup>®</sup>/Procrit<sup>®</sup> are used to treat anemia due to concomitant myelosuppressive chemotherapy.
- **Removal of the requirement for private practice-based clinics to return a copy of the Acknowledgment Form to the ESA APPRISE Oncology Program Call Center. Handle the forms as follows:**
  - Do not fax or mail a copy of the Acknowledgment Form to the ESA APPRISE Oncology Program Call Center.
  - Completed Acknowledgment Forms (or modified version consistent with the allowable changes) must be available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record.
  - In a private practice-based clinic, store the forms on-site and/or archive them through an electronic medical records system as long as they are retrievable.
  - The hospital process has not changed. In a hospital, provide the completed Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms.
- **A copy of the signed Acknowledgment Form must be provided to each patient. Please note that this is a new requirement.**
- **The Acknowledgment Form has been revised:**
  - ESA benefit information has been added in the section for patients. The risk language has been updated to focus on using ESA therapy for patients with cancer.

V2 10/13

**Please replace all previous unused versions of the Acknowledgment Form with version 5 10/13.**

The new version of the Acknowledgment Form will be mailed under separate cover. For Healthcare Providers in a private practice-based clinic, it will be sent to each practice location listed on your Program enrollment. For Hospital Designees, it will be sent for the hospitals for which you are responsible. In the meantime, you may access the Acknowledgment Form by visiting [www.esa-apprise.com](http://www.esa-apprise.com).

- **The Medication Guide is no longer a part of the REMS. It remains a part of the approved product label. Provide the Medication Guide to each patient at the initiation of each new course of ESA therapy and when it is materially revised or updated.**
- **The ESA APPRISE Oncology Program no longer requires re-enrollment for Healthcare Providers or Hospital Designees.**

V2 10/13



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## Selected Important Safety Information

### Cancer:

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
- To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid red blood cell (RBC) transfusions.
- Use ESAs only for anemia from myelosuppressive chemotherapy.
- ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- Discontinue following the completion of a chemotherapy course.

### Oncology Indication:

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:

- As a substitute for RBC transfusions in patients who require immediate correction of anemia.
- 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.

ESAs have not been shown to improve quality of life, fatigue, or patient well-being.

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## ESA APPRISE Oncology Program Overview

Three important points you should know about the ESA APPRISE Oncology Program.

### 1. What is the goal of the Program?

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.

### 2. What are the key Program requirements?

#### • TRAIN

Complete the ESA APPRISE Oncology Program training, which includes a review of the risks of ESA therapy and appropriate use of ESAs for patients with cancer.

#### • ENROLL

Enroll in the ESA APPRISE Oncology Program by completing the ESA APPRISE Oncology Program Enrollment Form.

#### • COUNSEL AND DOCUMENT

Prior to each new course of ESA therapy:

- Counsel each patient on the risks of ESAs using the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)\*. Review ESA risk:benefit information with your patient, and answer any questions they may have.
- Document that the ESA risk:benefit discussion occurred using the Acknowledgment Form. Complete each section of the Acknowledgment Form with each patient and provide each patient a copy of the signed form.
- Completed Acknowledgment Forms must be available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record.
- In a private practice-based clinic, store the forms on-site and/or archive them through an electronic medical record system as long as they are retrievable.
- In a hospital, provide the completed Acknowledgment Form to the Hospital Designee responsible for maintaining and storing the forms.

### 3. What happens if I do not train and enroll into the Program?

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

If you have questions regarding the ESA APPRISE Oncology Program, call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 or you may contact your local Amgen or Janssen Products, LP Field Representative.

[Training and Enrollment](#)

\*or modified version consistent with the allowable changes

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## Welcome to the ESA APPRISE Oncology Program

Train and enroll



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Recent Program Modifications

### Begin Training & Enrollment

Please confirm your enrollment in this program is related to the treatment of patients with cancer.

Yes  No

HCPs treating patients with an ESA for their cancer.

### What are the risks addressed through the ESA APPRISE Oncology Program?

- Increased risk of death and/or increased risk of tumor progression or recurrence in patients with cancer.
  - 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.

### Key Program Requirements

Healthcare Providers	Hospitals
1. Complete Training	1a. Select a Hospital Designee 1b. Hospital Designee Completes Training
2. Enroll in the ESA APPRISE Oncology Program	2. Enroll in the ESA APPRISE Oncology Program
3. Counsel and Document <ul style="list-style-type: none"> <li>Counsel each patient on the risks of ESAs prior to each new course of ESA therapy.</li> <li>Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form and providing each patient a copy of the signed form.</li> </ul>	3. Implement <ul style="list-style-type: none"> <li>Hospital Designee to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program.</li> </ul>

The [ESA APPRISE Oncology Program training and enrollment](#) takes you step-by-step through the required training and enrollment process.

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

### Questions about the ESA APPRISE Oncology Program?

If you need more information about the ESA APPRISE Oncology Program:

- Call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089, or
- Contact your local Amgen or Janssen Products, LP Field Representative

\*Additional information on REMS may be found at [www.FDA.gov](http://www.FDA.gov)

Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

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# Welcome to the ESA APPRISE Oncology Program

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## Begin Training & Enrollment

Please confirm your enrollment in this program is related to the treatment of patients with cancer.

Yes  No

The ESA APPRISE Oncology Program is solely intended for the purposes of treating patients with cancer.

[Non-prescribing HCPs-Training only \(click here\)](#)

Close

- 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.

### Key Program Requirements

Healthcare Providers	Hospitals
<b>1. Complete Training</b>	<b>1a. Select a Hospital Designee</b> <b>1b. Hospital Designee Completes Training</b>
<b>2. Enroll in the ESA APPRISE Oncology Program</b>	<b>2. Enroll in the ESA APPRISE Oncology Program</b>
<b>3. Counsel and Document</b> <ul style="list-style-type: none"> <li>Counsel each patient on the risks of ESAs prior to each new course of ESA therapy.</li> <li>Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form and providing each patient a copy of the signed form.</li> </ul>	<b>3. Implement</b> <ul style="list-style-type: none"> <li>Hospital Designee to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program.</li> </ul>

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

### Questions about the ESA APPRISE Oncology Program?

If you need more information about the ESA APPRISE Oncology Program:

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# Welcome to the ESA APPRISE Oncology Program

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## Begin Training & Enrollment

To ensure that you are directed to the appropriate ESA APPRISE Oncology Program Training and Enrollment Module, please select the option that best describes you.

- I am an HCP who prescribes ESAs
- I am the authorized designee enrolling on behalf of a Hospital

[Start](#)

### What are the risks addressed through the ESA APPRISE Oncology Program?

- **Increased risk of death and/or increased risk of tumor progression or recurrence in patients with cancer.**
  - 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.

### Key Program Requirements

Healthcare Providers	Hospitals
1. Complete Training	1a. Select a Hospital Designee 1b. Hospital Designee Completes Training
2. Enroll in the ESA APPRISE Oncology Program	2. Enroll in the ESA APPRISE Oncology Program
3. Counsel and Document <ul style="list-style-type: none"> <li>• Counsel each patient on the risks of ESAs prior to each new course of ESA therapy.</li> <li>• Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form and providing each patient a copy of the signed form.</li> </ul>	3. Implement <ul style="list-style-type: none"> <li>• Hospital Designee to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program.</li> </ul>

The [ESA APPRISE Oncology Program training and enrollment](#) takes you step-by-step through the required training and enrollment process.

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

### Questions about the ESA APPRISE Oncology Program?

If you need more information about the ESA APPRISE Oncology Program:

- Call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089, or
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## 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.

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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## 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

### 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).

### 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 ≥ 14 and ≥ 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).

### 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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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

You must respond to the following question to advance to the next section

**Have you reviewed all of Section 1: Key Safety Information for Use of ESAs in Patients With Cancer?**

**Yes, I have reviewed all of Section 1**

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## 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.

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You must respond to the following question to advance to the next section

**Have you reviewed all of Section 2: Appropriate Use of ESAs for Patients With Cancer?**

**Yes, I have reviewed all of Section 2  
Click here to proceed to Knowledge Check**

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## 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.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following chemotherapy.

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Medication Guides.

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### Healthcare Provider Knowledge Check

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

True

False

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

Yes, I have reviewed all of Section 2  
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## 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.
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  - in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - in patients with cancer receiving myelosuppressive chemotherapy.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following chemotherapy.

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Medication Guides.

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### Healthcare Provider Knowledge Check

Correct.

ESAs are not indicated for the treatment of anemia for patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.

Next

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

Yes, I have reviewed all of Section 2  
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## 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 chemotherapy with the intent to cure.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

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Medication Guides.

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### Healthcare Provider Knowledge Check

Incorrect.

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

Next

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

Yes, I have reviewed all of Section 2  
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## 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 anti-angiogenic agents, unless also receiving concomitant myelosuppressive chemotherapy.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy when hemoglobin level is less than 11 g/dL.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

Please see the Aranesp<sup>®</sup>, E

Medication Guides.

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

Aranesp<sup>®</sup> and Epogen<sup>®</sup>/Procrit<sup>®</sup> are different drugs with distinct dosing schedules.

### Healthcare Provider Knowledge Check

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

True

False

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

Yes, I have reviewed all of Section 2  
Click here to proceed to Knowledge Check

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## 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 anti-angiogenic agents.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following chemotherapy.

Please see the Aranesp®, E

Medication Guides.

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.

### Healthcare Provider Knowledge Check

Incorrect.

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

Next

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

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## 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 immunosuppressive therapy.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy when hemoglobin level is less than 10 g/dL.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

Please see the Aranesp®, E

Medication Guides.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

### Healthcare Provider Knowledge Check

Correct.

Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy only when hemoglobin level is less than 10 g/dL.

Next

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

Yes, I have reviewed all of Section 2  
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## 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 anti-angiogenic agents.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

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Medication Guides.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

### Healthcare Provider Knowledge Check

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

True

False

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

Yes, I have reviewed all of Section 2  
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## 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 anti-angiogenic agents.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

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Medication Guides.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

### Healthcare Provider Knowledge Check

Correct.

ESAs should be discontinued following the completion of a chemotherapy course.

[Continue to Section 3](#)

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

[Yes, I have reviewed all of Section 2  
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## 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 anti-angiogenic agents.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

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Medication Guides.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

### Healthcare Provider Knowledge Check

Incorrect.

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

[Continue to Section 3](#)

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

[Yes, I have reviewed all of Section 2  
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## Section 3: Program Requirements and Materials for Healthcare Providers

### HCP requirements for patient counseling

The ESA APPRISE Oncology Program requires HCPs to counsel patients in the following manner:

- 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 Acknowledgment Form.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form with each patient and providing each patient a copy of the signed form.



[CLICK HERE](#)

- Completed Acknowledgment Forms (or modified version consistent with the allowable changes) must be available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record.
- In a private practice-based clinic, store the forms on-site and/or archive them through an electronic medical records system as long as they are retrievable.
- In a hospital, provide the completed Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms.
- 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.



[CLICK HERE](#)

**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 ask your local Amgen or Janssen Products, LP Field Representative.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

You must respond to the following question to advance to the next section

**Have you reviewed all of Section 3: Program Requirements and Materials for Healthcare Providers?**

**Yes. I have reviewed all of Section 3**

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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**

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You must respond to the following question to advance to the next section

**Have you reviewed all of *Section 4: Healthcare Provider Enrollment*?**

**Yes, I have reviewed all of Section 4**

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## ESA APPRISE Oncology Program Enrollment for Healthcare Providers

**I agree to the following:**

I have reviewed the appropriate current prescribing information and Medication Guide 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 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.

<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 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>

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

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You must agree to the above to advance to the enrollment form

**I have completed the ESA APPRISE Program Training Module. I understand that failure to comply with the ESA APPRISE Oncology Program requirements will result in suspension of my access to ESAs.**

**Yes, I agree to all the above**

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## ESA APPRISE Oncology Program Enrollment for Healthcare Providers

\* indicates a required field.

### Prescriber Information

**My primary practice location is (select one)** \*

Private practice-based clinic

Hospital or outpatient facility affiliated with a hospital/institution

**First Name** \*

**Last Name** \*

**Professional Designation** \*

**Title**

**Email Address** \*

**Confirm Email Address** \*

**NPI #** \*

- or -

**State/Territory License # and Issuing State** \*

### Electronic Signature

Your signature and date are required to complete your enrollment. Please enter your name and date in the space provided. This will serve as your electronic signature and will certify that you have read and agree with the terms provided.

**Signature** \*

**Date** \*

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## ESA APPRISE Oncology Program Enrollment for Healthcare Providers

⊕ indicates a required field.

### Primary Practice Location

Please provide ZIP code or city/state to find your Primary Practice Location

ZIP  - or - City  State

Please select your Primary Practice Location

#### Primary Practice Search Results

Practice Name ⊕	Address	City	State	ZIP Code

Primary practice is not listed

### Primary Practice Contact Information

Same as Contact Information and Primary Location Address

**First Name** ⊕

**Last Name** ⊕

**Address** ⊕

**City** ⊕

**State** ⊕

**ZIP Code** ⊕

**Email Address** ⊕

**Confirm Email Address** ⊕

**Phone (###-###-####)** ⊕

**Fax (###-###-####)** ⊕

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## ESA APPRISE Oncology Program Enrollment for Healthcare Providers

⊕ indicates a required field.

### Primary Practice Location

**Primary Practice Name** ⊕

**Address** ⊕

**City** ⊕

**State** ⊕

**ZIP Code** ⊕

Search by ZIP code or City/State

### Primary Practice Contact Information

Same as Contact Information  
and Primary Location Address

**First Name** ⊕

**Last Name** ⊕

**Address** ⊕

**City** ⊕

**State** ⊕

**ZIP Code** ⊕

**Email Address** ⊕

**Confirm Email Address** ⊕

**Phone (###-###-####)** ⊕

**Fax (###-###-####)** ⊕

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## ESA APPRISE Oncology Program Enrollment for Healthcare Providers

\* indicates a required field.

### Primary Practice Address Match

The address you entered has returned similar entries in the ESA APPRISE Oncology Program address database. The address you entered follows:

**New Practice Name  
1001 Main Blvd  
Los Angeles, CA 90001**

Please select an address already available in the ESA APPRISE Oncology Program below or confirm your address.

- NEW PRACTICE NAME MAIN  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**
- NEW PRACTICE  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**
- NEW PRACTICE MAIN  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**
- NEW PRACTICE MAIN  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**
- NEW PRACTICE NAME MAIN  
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1001 MAIN BLVD  
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1001 MAIN BLVD  
LOS ANGELES, CA 90001**
- NEW PRACTICE MAIN  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**
- NEW PRACTICE NAME MAIN  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**
- NEW PRACTICE NAME MAIN  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**

Your entered address:

- New Practice Name  
1001 Main Blvd  
Los Angeles, CA 90001**

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## ESA APPRISE Oncology Program Enrollment for Healthcare Providers

⊛ indicates a required field.

### Additional Practice Locations

Enter in a combination of up to 3 ZIP codes or City/State combinations to search for additional affiliation sites to enroll.

ZIP		- or -	City		State	
<input type="text"/>			<input type="text"/>		<input type="text"/>	▼
ZIP		- or -	City		State	
<input type="text"/>			<input type="text"/>		<input type="text"/>	▼
ZIP		- or -	City		State	
<input type="text"/>			<input type="text"/>		<input type="text"/>	▼

Please select up to 10 Secondary Practice Locations

#### Secondary Practice Search Results

<input type="checkbox"/>	Practice Name	Address	City	State	ZIP Code

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## ESA APPRISE Oncology Program Enrollment for Healthcare Providers

Thank you for participating in the ESA APPRISE Oncology Program

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**Your enrollment is now complete.** Below is your ESA APPRISE Oncology Program enrollment identification (ID) number along with a list of the site affiliation(s) you provided.

**Enrollment ID: 123456**

Your Enrollment ID will be required on every ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form.

**Site Affiliation(s)**

Site ID	Site Name	Site Address	City	State	Zip	Affiliation(s)
123456	XYZ	123 E MAIN ST	Scottsdale	AZ	85225	Primary
66789	XYZ	123 E MAIN ST	Scottsdale	AZ	85225	Secondary

You will receive the materials for the ESA APPRISE Oncology Program. The materials will be shipped to each private practice location in the above list. 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

Until your materials arrive you can [download and print the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form](#).

For questions regarding the ESA APPRISE Oncology Program, please visit the ESA APPRISE Oncology Program [Frequently Asked Questions](#) page, call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 or contact your local Amgen or Janssen Products, LP Field Representative.

**Print this confirmation notice. It is recommended that it be kept in a safe location as you will need to reference your enrollment number to access your profile.**

An email has also been sent confirming your enrollment. If you do not receive a confirmation email, please check your email spam folder.

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## Training Module for Hospital Designees

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 Hospital Designees at hospitals that 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 the hospital's 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 as well as the requirements for Hospital Designees who must oversee implementation of this safety program at their respective Hospitals.

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 and Hospital Designee Program requirements and materials**

**Section 4: Enrollment**

Please see the Aranesp®, Epogen® and Procrit® prescribing information, including Boxed WARNINGS and Medication Guides.

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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

### 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).

### 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 ≥ 14 and ≥ 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).

### 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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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

You must respond to the following question to advance to the next section

Have you reviewed all of Section 1: Key Safety Information for Use of ESAs in Patients With Cancer?

**Yes, I have reviewed all of Section 1**

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## 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.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

You must respond to the following question to advance to the next section

**Have you reviewed all of Section 2: Appropriate Use of ESAs for Patients With Cancer?**

**Yes, I have reviewed all of Section 2  
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- 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 anti-angiogenic agents.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following transfusion.

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Medication Guides.

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### Hospital Designee Knowledge Check

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

True

False

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

Yes, I have reviewed all of Section 2  
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  - in patients with cancer receiving myelosuppressive chemotherapy.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following chemotherapy.

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Medication Guides.

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### Hospital Designee Knowledge Check

Correct.

ESAs are not indicated for the treatment of anemia for patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.

Next

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

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## Section 2: Appropriate Use of ESAs for Patients With Cancer

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  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following chemotherapy.

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Medication Guides.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

### Hospital Designee Knowledge Check

Incorrect.

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

Next

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

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  - in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - in patients with cancer receiving anti-angiogenic agents, unless also receiving concomitant myelosuppressive chemotherapy.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy when hemoglobin level is less than 11 g/dL.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

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Medication Guides.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.

### Hospital Designee Knowledge Check

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

True

False

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

Yes, I have reviewed all of Section 2  
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  - in patients with cancer receiving anti-angiogenic agents.
  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy only when hemoglobin level is less than 10 g/dL.
- Use the lowest dose of ESA.
- Discontinue ESAs following transfusion of RBCs.

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### Hospital Designee Knowledge Check

Incorrect.

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

Next

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

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  - as a substitute for RBC transfusion.
- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy only when hemoglobin level is less than 10 g/dL.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

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### Hospital Designee Knowledge Check

Correct.

Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy only when hemoglobin level is less than 10 g/dL.

Next

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

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- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

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### Hospital Designee Knowledge Check

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

True

False

You must respond to the following question to advance to the next section

**Have you reviewed all of Section 2: Appropriate Use of ESAs for Patients With Cancer?**

Yes, I have reviewed all of Section 2  
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- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA.
- Discontinue ESAs following the completion of chemotherapy.

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### Hospital Designee Knowledge Check

Correct.

ESAs should be discontinued following the completion of a chemotherapy course.

[Continue to Section 3](#)

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

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- ESAs have not been shown to improve overall survival.

### Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
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- Discontinue ESAs following the completion of chemotherapy.

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### Hospital Designee Knowledge Check

Incorrect.

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

[Continue to Section 3](#)

You must respond to the following question to advance to the next section

Have you reviewed all of *Section 2: Appropriate Use of ESAs for Patients With Cancer*?

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## Section 3: Program Requirements and Materials for Healthcare Providers and Hospital Designees

### HCP requirements for patient counseling

The ESA APPRISE Oncology Program requires HCPs to counsel patients in the following manner:

- 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 Acknowledgment Form.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with each patient has occurred by completing each section of the Acknowledgment Form with each patient and providing each patient a copy of the signed form.



[CLICK HERE](#)

- Completed Acknowledgment Forms (or modified version consistent with the allowable changes) must be available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record.
- In a private practice-based clinic, store the forms on-site and/or archive them through an electronic medical records system as long as they are retrievable.
- In a hospital, provide the completed Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms.

### Hospital Designee Requirements

- Assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in the hospital(s) for which you are responsible.
- Complete the Training Module for Hospital Designees.
- Understand that if HCPs in the hospital prescribe Aranesp® or Epogen®/Procrit® to patients with cancer, failure to comply with Program requirements will lead to suspension of access to ESAs for the hospital.
- Inform all HCPs who prescribe Aranesp® or Epogen®/Procrit® for patients with cancer at the hospital of the Program training and certification requirements.
- Establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the ESA APPRISE Oncology Program, such that:
  - ESAs are only dispensed to patients with cancer after verifying:
    - that the HCP who prescribes ESAs for patients with cancer is certified in the Program; and
    - that the discussion between the patient and the Program-certified provider on the risks of ESA therapy is documented by patient and provider signatures on the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form prior to initiation of each new course of ESA therapy.
  - If an HCP who prescribes ESAs is not certified in the ESA APPRISE Oncology Program, the provider will be notified that they are not able to prescribe ESAs for patients with cancer.
- Oversee compliance with Program auditing to assess the effectiveness of the Program.
- Maintain evidence of compliance with the Program for auditing purposes, as follows:
  - Documentation (ie, unique enrollment ID number) that each HCP in the hospital who prescribes ESAs for patients with cancer is certified in the Program.
  - Documentation of the risk:benefit discussion between certified provider and patient on the Acknowledgment Form for each patient with cancer for whom an Aranesp® or Epogen®/Procrit® prescription was filled; the Acknowledgment Forms are to be stored on-site and/or archived in a retrievable manner.
- Completed Acknowledgment Forms (or modified version consistent with the allowable changes) must be available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record.
- 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.



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Please see the Aranesp®, Epogen® and Procrit® prescribing information, including **Boxed WARNINGS** and Medication Guides.

**Failure to comply with the ESA APPRISE Oncology Program requirements will result in suspension of the hospital's access to ESAs.**

Upon completion of this enrollment process, you (and an alternate contact, if provided) will receive an email (or fax if no email address is provided) with the ESA APPRISE Oncology Program enrollment ID number unique to the hospital. This enrollment ID number allows you to identify HCPs enrolled at your location, by clicking "Login" at the top right of the ESA APPRISE Oncology Program website home page. You can also order more Program materials via [www.esa-apprise.com](http://www.esa-apprise.com) using the hospital enrollment ID number.

Once you have enrolled, you will receive the following materials to assist HCPs in the hospital in implementing the Program:

- 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
- Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to 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 ask your local Amgen or Janssen Products, LP Field Representative.

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You must respond to the following question to advance to the next section

**Have you reviewed all of Section 3: Program Requirements and Materials for Healthcare Providers and Hospital Designees?**

**Yes, I have reviewed all of Section 3**

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## Section 4: Hospital Designee 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, and commits you to complying with the Program requirements.

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

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You must respond to the following question to advance to the next section

**Have you reviewed all of *Section 4: Hospital Designee Enrollment*?**

**Yes, I have reviewed all of Section 4**

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## ESA APPRISE Oncology Program Enrollment for Hospitals

I agree to the following on behalf of the hospital(s) for which I am responsible:

- I have been designated by hospital management to assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in the hospital(s) for which I will enroll as the Designee.
- I have completed the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- I understand that if healthcare providers (HCPs) in the hospital prescribe Aranesp® or Epogen®/Procrit® to patients with cancer, failure of the staff to comply with enrollment requirements will lead to suspension of access to Aranesp® and Epogen®/Procrit® for the hospital.
- I will inform all HCPs who prescribe Aranesp® or Epogen®/Procrit® for patients with cancer at the hospital of the ESA APPRISE Oncology Program training and certification requirements.
- I will establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program, such that:
  - Aranesp® or Epogen®/Procrit® are only dispensed to patients with cancer after verifying:
    - that the HCP who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer has enrolled in the Program; and
    - that the discussion between the patient and the Program-certified provider on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and provider signatures on the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form prior to initiation of each new course of Aranesp® or Epogen®/Procrit® therapy.
  - If an HCP that prescribes Aranesp® or Epogen®/Procrit® is not enrolled in the Program, the provider will be notified that they are not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
- I am authorized to oversee compliance with Program auditing to assess the effectiveness of the Program.
- I will maintain evidence of compliance with the ESA APPRISE Oncology Program for auditing purposes, as follows:
  - Documentation (ie, unique enrollment ID number) that each HCP in the hospital who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is enrolled in the Program.
  - Documentation of the risk:benefit discussion between certified provider and patient on the Acknowledgment Form for each patient with cancer for whom an Aranesp® or Epogen®/Procrit® prescription was filled.

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

You must agree to the above to advance to the enrollment form

**I have completed the ESA APPRISE Oncology Program Training Module. I understand that failure to comply with the ESA APPRISE Oncology Program requirements will result in suspension of the hospital's access to ESAs.**

**Yes, I agree to all the above**

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## ESA APPRISE Oncology Program Enrollment for Hospitals

\* indicates a required field.

### Authorized Hospital Designee Information

<b>First Name *</b>	<input type="text"/>
<b>Last Name *</b>	<input type="text"/>
<b>Title</b>	<input type="text"/>
<b>Email Address *</b>	<input type="text"/>
<b>Confirm Email Address *</b>	<input type="text"/>
<b>Password *</b>	<input type="password"/>
<b>Confirm Password *</b>	<input type="password"/>
<b>Phone (###-###-####) *</b>	<input type="text"/>
<b>Fax (###-###-####) *</b>	<input type="text"/>

**Hospital Summary Report Opt-in**

Please send an email notification to the hospital email address listed above that summarizes all HCPs enrolled in the ESA APPRISE Oncology Program at the hospital each time a new HCP affiliated with the hospital enrolls in the Program. Note: You will automatically be notified of all HCP enrollment terminations, whether voluntary or for cause.

### Electronic Signature

Your signature and date are required to complete your enrollment. Please enter your name and date in the space provided. This will serve as your electronic signature and will certify that you have read and agree with the terms provided.

<b>Signature *</b>	<input type="text" value="First and Last Name"/>
<b>Date *</b>	<input type="text" value="Today's date (mm/dd/yyyy)"/>

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## ESA APPRISE Oncology Program Enrollment for Hospitals

 indicates a required field.


### Hospital Enrollment Information

Please provide ZIP code or city/state to find your Hospital Main Address

ZIP  - or - City  State

Please select your hospital

#### Hospital Main Address Search Results

Practice Name 	Address	City	State	ZIP Code

Hospital main address is not listed

### Hospital Contact Information for Receipt of Program Materials

Click here if different from the authorized designee

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## ESA APPRISE Oncology Program Enrollment for Hospitals

\* indicates a required field.

### Hospital Enrollment Information

Hospital Name \*

Address \*

City \*

State \*

ZIP Code \*

HIN # \*

- or -

DDD # \*

Search by ZIP code or City/State

### Hospital Contact Information for Receipt of Program Materials

Click here if different from the authorized designee

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## ESA APPRISE Oncology Program Enrollment for Hospitals

⊕ indicates a required field.

### Hospital Enrollment Information

Please provide ZIP code or city/state to find your Hospital Main Address

ZIP  - or - City  State

Please select your hospital

#### Hospital Main Address Search Results

Practice Name	Address	City	State	ZIP Code

Hospital main address is not listed

### Hospital Contact Information for Receipt of Program Materials

**First Name** ⊕

**Last Name** ⊕

Same as hospital main address

**Address** ⊕

**City** ⊕

**State** ⊕

**ZIP Code** ⊕

**Email Address** ⊕

**Confirm Email Address** ⊕

**Password** ⊕

**Confirm Password** ⊕

**Phone (###-###-####)** ⊕

**Fax (###-###-####)** ⊕

**Hospital Summary Report Opt-in**

Please send an email notification to the hospital email address listed above that summarizes all HCPs enrolled in the ESA APPRISE Oncology Program at the hospital each time a new HCP affiliated with the hospital enrolls in the Program. Note: You will automatically be notified of all HCP enrollment terminations, whether voluntary or for cause.

Click here if contact is the same as the authorized designee

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## ESA APPRISE Oncology Program Enrollment for Hospitals

\* indicates a required field.

### Hospital Enrollment Information

Hospital Name \*

Address \*

City \*

State \*

ZIP Code \*

HIN # \*

- or -

DDD # \*

Search by ZIP code or City/State

### Hospital Contact Information for Receipt of Program Materials

First Name \*

Last Name \*

Same as hospital main address

Address \*

City \*

State \*

ZIP Code \*

Email Address \*

Confirm Email Address \*

Password \*

Confirm Password \*

Phone (###-###-####) \*

Fax (###-###-####) \*

**Hospital Summary Report Opt-in**

Please send an email notification to the hospital email address listed above that summarizes all HCPs enrolled in the ESA APPRISE Oncology Program at the hospital each time a new HCP affiliated with the hospital enrolls in the Program. Note: You will automatically be notified of all HCP enrollment terminations, whether voluntary or for cause.

Click here if contact is the same as the authorized designee

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## ESA APPRISE Oncology Program Enrollment for Hospitals

\* indicates a required field.

### Hospital Enrollment Information Address Match

The address you entered has returned similar entries in the ESA APPRISE Oncology Program address database.  
The address you entered follows:

**New Hospital Name  
1001 Main Blvd  
Los Angeles, CA 90001**

Please select an address already available in the ESA APPRISE Oncology Program below or confirm your address.

**NEW HOSPITAL NAME MAIN  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**

**NEW HOSPITAL  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**

**NEW HOSPITAL MAIN  
1001 MAIN BLVD  
LOS ANGELES, CA 90001**

Your entered address:

**New Hospital Name  
1001 Main Blvd  
Los Angeles, CA 90001**

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## ESA APPRISE Oncology Program Enrollment for Hospitals

Thank you for participating in the ESA APPRISE Oncology Program

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**Your enrollment is now complete.** Below is your ESA APPRISE Oncology Program enrollment identification (ID) number.

**Enrollment ID: 123456**

This enrollment ID number allows you to identify HCPs enrolled at your location.

### Enrolled Hospital

Site ID	Site Name	Site Address	City	State	Zip
7890	Phoenix Hospital	112 Elm	Phoenix	AZ	85027

You will receive the required materials for the Program for HCPs in the hospital.

Materials provided 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
- Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer

Until your materials arrive, [download and print the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form](#).

For questions regarding the ESA APPRISE Oncology Program, please visit the ESA APPRISE Oncology Program [Frequently Asked Questions](#) page, call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 or contact your local Amgen or Janssen Products, LP Field Representative.

**Print this confirmation notice. It is recommended that it be kept in a safe location as you will need to reference your enrollment number to access your profile.**

An email has also been sent confirming your enrollment. If you do not receive a confirmation email, please check your email spam folder.

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### Materials for Healthcare Providers

#### Order Program Materials

Medication Guides and Acknowledgment Forms can be delivered to your practice location. To begin, enter in your [Enrollment ID](#) and click the continue button below.

Enrollment ID:

[Continue](#)

#### Healthcare Provider and Hospital Designee Materials

- [Dear Healthcare Provider \(DHCP\) Letter to Newly Identified HCPs who may Prescribe, or Prescribe and Dispense, ESAs for Patients with Cancer](#)
- [Dear Healthcare Provider \(DHCP\) Letter to Directors of Pharmacy/Administrators of Newly Identified Hospitals That Dispense ESAs to Patients With Cancer](#)
- [Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer](#)
- [Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer](#)
- [ESA APPRISE Oncology Program Training Module for Healthcare Providers](#)
- [ESA APPRISE Oncology Program Training Module for Hospital Designees](#)
- [ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers](#)
- [ESA APPRISE Oncology Program Enrollment Form for Hospitals](#)
- [ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form \(Acknowledgment Form\)](#)
- [Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics](#)
- [ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form \(Acknowledgment Form\) - SPANISH](#)

#### Prescribing Information

- [Aranesp® \(darbepoetin alfa\) Prescribing Information](#)
- [Epogen® \(epoetin alfa\) Prescribing Information](#)
- [Procrit® \(epoetin alfa\) Prescribing Information](#)

### Materials for Patients

#### Acknowledgment Form

- [ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form \(Acknowledgment Form\)](#)
- [ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form \(Acknowledgment Form\) - SPANISH](#)

#### Medication Guides

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- [Aranesp® \(darbepoetin alfa\) Medication Guide - SPANISH](#)
- [Epogen® \(epoetin alfa\) Medication Guide](#)
- [Epogen® \(epoetin alfa\) Medication Guide - SPANISH](#)
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#### Instructions for Use

- [Aranesp® \(darbepoetin alfa\) Instructions for Use - Single-Dose Vial](#)
- [Aranesp® \(darbepoetin alfa\) Instructions for Use - Single-Dose Prefilled Syringe \(SingleJect®\)](#)
- [Epogen® \(epoetin alfa\) Instructions for Use](#)
- [Procrit® \(epoetin alfa\) Instructions for Use](#)

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## Material Order: Address Selection

### Personal Information

The Enrollment ID is associated to the following individual.

**First Name** John

**Last Name** Smith

**Email Address** john.smith@email.com

### Practice Locations

Please select/enter your shipping address

Practice Locations				
Practice Name 	Address	City	State	ZIP Code
Practice Name	1234 N MAIN ST	WAYNE	PA	19087

Primary practice is not listed

### Practice Contact Information

Confirm the following contact information is correct

**First Name** Allison

**Last Name** Tennant

**Email Address** allison.tennant@email.com

**Phone (###-###-####)** 215-555-1212

**Fax (###-###-####)** 215-555-1213

Primary contact is not listed

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**First Name** John

**Last Name** Smith

**Email Address** john.smith@email.com

### Practice Locations

**Primary Practice Name** \*

**Address** \*

**City** \*

**State** \*

**ZIP Code** \*

Select from the list of registered sites

### Practice Contact Information

Confirm the following contact information is correct

**First Name** Allison

**Last Name** Tennant

**Email Address** allison.tennant@email.com

**Phone (###-###-####)** 215-555-1212

**Fax (###-###-####)** 215-555-1213

Primary contact is not listed

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Please select/enter your shipping address

Practice Locations				
Practice Name	Address	City	State	ZIP Code
Practice Name	1234 N MAIN ST	WAYNE	PA	19087

Primary practice is not listed

### Practice Contact Information

**First Name \***

**Last Name \***

**Email Address \***

**Phone (###-###-####) \***

**Fax (###-###-####) \***

Select the registered primary contact

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The Enrollment ID is associated to the following individual.

**First Name** John

**Last Name** Smith

**Email Address** john.smith@email.com

### Practice Locations

**Primary Practice Name** \*

**Address** \*

**City** \*

**State** \*

**ZIP Code** \*

Select from the list of registered sites

### Practice Contact Information

**First Name** \*

**Last Name** \*

**Email Address** \*

**Phone (###-###-####)** \*

**Fax (###-###-####)** \*

Select the registered primary contact

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## Material Order: Specify Type and Quantity

### Materials Selection

Select the materials you would like to order

Quantity	Item
----------	------

#### Medication Guides

- |                                  |  |
|----------------------------------|--|
| <input type="text" value="0"/> ▼ | Aranesp® (darbepoetin alfa) Medication Guide           |
| <input type="text" value="0"/> ▼ | Aranesp® (darbepoetin alfa) Medication Guide - SPANISH |
| <input type="text" value="0"/> ▼ | Epogen® (epoetin alfa) Medication Guide                |
| <input type="text" value="0"/> ▼ | Epogen® (epoetin alfa) Medication Guide - SPANISH      |
| <input type="text" value="0"/> ▼ | Procrit® (epoetin alfa) Medication Guide               |
| <input type="text" value="0"/> ▼ | Procrit® (epoetin alfa) Medication Guide - SPANISH     |

#### Tear Pads

- |                                  |  |
|----------------------------------|--|
| <input type="text" value="0"/> ▼ | Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms           |
| <input type="text" value="0"/> ▼ | Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms - SPANISH |

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## Material Order: Your Current Order Items

### Current Order

The items that you have selected are listed below.

Quantity	Order Item
5	Aranesp® (darbepoetin alfa) Medication Guide
10	Epogen® (epoetin alfa) Medication Guide
15	Procrit® (epoetin alfa) Medication Guide
25	Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms

### Delivered to the following location

Practice Name  
1234 N MAIN ST  
WAYNE, PA 19087

Your order is not submitted until you click **Submit Order** below.

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## Material Order: Your Current Order Items

 [Print this Page](#)

**Your order has been received and the confirmation number is 012345678.**

An email will also be sent confirming your order along with a confirmation number. If you do not receive a confirmation email, please check your email spam folder.

### Order Summary

Quantity	Order Item
5	Aranesp® (darbepoetin alfa) Medication Guide
10	Epogen® (epoetin alfa) Medication Guide
15	Procrit® (epoetin alfa) Medication Guide
25	Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms

### Delivered to

Practice Name  
1234 N MAIN ST  
WAYNE, PA 19087

You may continue with [another order to a different, associated shipping address](#) or [enter in a new Enrollment ID](#) to order materials.

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## Forms & Resources

### Materials for Healthcare Providers

#### Order Program Materials

Medication Guides and Acknowledgment Forms can be delivered to your practice location. To begin, enter in your Enrollment ID and click the continue button below.

Enrollment ID:

[Continue](#)

#### Download Your Customized Acknowledgment Form



To download the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form, enter your Enrollment ID and click Next. Your Enrollment ID can be obtained in your enrollment confirmation email.

Enrollment ID

[Cancel](#)

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Hea



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[Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics](#)

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[Epogen® \(epoetin alfa\) Prescribing Information](#)

[Procrit® \(epoetin alfa\) Prescribing Information](#)

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##### Acknowledgment Form

[ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form \(Acknowledgment Form\)](#)

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[Epogen® \(epoetin alfa\) Medication Guide](#)

[Epogen® \(epoetin alfa\) Medication Guide - SPANISH](#)

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##### Instructions for Use

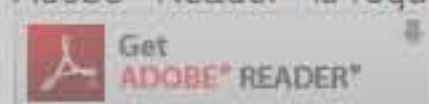
[Aranesp® \(darbepoetin alfa\) Instructions for Use - Single-Dose Vial](#)

[Aranesp® \(darbepoetin alfa\) Instructions for Use - Single-Dose Prefilled Syringe \(SingleJect®\)](#)

[Epogen® \(epoetin alfa\) Instructions for Use](#)

[Procrit® \(epoetin alfa\) Instructions for Use](#)

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### Materials for Healthcare Providers

#### Order Program Materials

Medication Guides and Acknowledgment Forms can be delivered to your practice location. To begin, enter in your Enrollment ID and click the continue button below.

Enrollment ID:

[Continue](#)

#### Download Your Customized Acknowledgment Form

Click the Practice Name to download the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form for that location.

##### Forms Available to Download

Name	Address	City	State	ZIP Code
<a href="#">Dakota Health System</a>	123 Main St	Los Angeles	CA	90001
<a href="#">Imperial Point Medical Center</a>	456 Race St	Los Angeles	CA	90001
<a href="#">Sibley Memorial Hospital</a>	123 Main St	Los Angeles	CA	90001
<a href="#">AMI Culver Union Hospital</a>	456 Race St	Los Angeles	CA	90001

[ESA APPRISE Oncology Program Enrollment Form for Hospitals](#)

[ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form \(Acknowledgment Form\)](#)

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[ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form \(Acknowledgment Form\) - SPANISH](#)

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[Epogen® \(epoetin alfa\) Medication Guide - SPANISH](#)

[Procrit® \(epoetin alfa\) Medication Guide](#)

[Procrit® \(epoetin alfa\) Medication Guide - SPANISH](#)

##### Instructions for Use

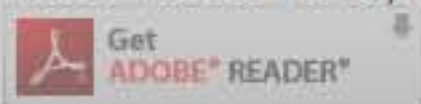
[Aranesp® \(darbepoetin alfa\) Instructions for Use - Single-Dose Vial](#)

[Aranesp® \(darbepoetin alfa\) Instructions for Use - Single-Dose Prefilled Syringe \(SingleJect®\)](#)

[Epogen® \(epoetin alfa\) Instructions for Use](#)

[Procrit® \(epoetin alfa\) Instructions for Use](#)

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## ESA APPRISE Oncology Program Login

**Username**

**Password**

Login

[First time user? Forgot password? Click here.](#)

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## Password Assistance

### Forgotten Password

Enter in the username you use to access the site and an email will be sent that will provide you information to login.

**Username**

**Confirm Username**

### First Time Users

Enter in your Enrollment ID and an email with instructions for how to login will be sent to the associated email on record.

**Enrollment ID**

**Confirm Enrollment ID**

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## ESA APPRISE Oncology Program Healthcare Provider

### Practice Location Management

Add and remove practice locations.

### Edit Profile

Review and edit your contact information.

### Change Password

Change your password.

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[ESA APPRISE Oncology Program Healthcare Provider](#) » Practice Location Management

## Practice Location Management

### Practice Locations

<input type="checkbox"/>	Practice Name	Address	City	State	ZIP Code
<input type="checkbox"/>	Dakota Health System	123 Main St	Los Angeles	CA	90001
<input type="checkbox"/>	Imperial Point Medical Center	456 Race St	Los Angeles	CA	90001
<input type="checkbox"/>	Sibley Memorial Hospital	123 Main St	Los Angeles	CA	90001
<input type="checkbox"/>	AMI Culver Union Hospital	456 Race St	Los Angeles	CA	90001

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[Remove Practice Location](#)

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[ESA APPRISE Oncology Program Healthcare Provider](#) » [Practice Location Management](#) » [Add Practice Location](#)

## Add Practice Location

### Practice Location Lookup

ZIP  - or - City  State

#### Practice Location Search Results

Practice Name	Address	City	State	ZIP Code
---------------	---------	------	-------	----------

Practice location not listed

### Practice Contact Information

**First Name**

**Last Name**

Address same as Practice Location information above

**Address**

**City**

**State**

**ZIP Code**

**Email Address**

**Confirm Email Address**

**Phone (###-###-####)**

**Fax (###-###-####)**

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## Add Practice Location

### Practice Location Lookup

**Practice Name**

**Address**

**City**

**State**

**ZIP Code**

Search by ZIP code or City/State

### Practice Contact Information

**First Name**

**Last Name**

Address same as Practice Location information above

**Address**

**City**

**State**

**ZIP Code**

**Email Address**

**Confirm Email Address**

**Phone (###-###-####)**

**Fax (###-###-####)**

[Cancel](#)

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ESA APPRISE Oncology Program Healthcare Provider - Practice Location Management

## Practice Location

### Practice Locations

<input type="checkbox"/>	Practice Name
<input checked="" type="checkbox"/>	Dakota Health System
<input type="checkbox"/>	Imperial Point Medical C
<input type="checkbox"/>	Sibley Memorial Hospita
<input type="checkbox"/>	AMI Culver Union Hospit

ZIP Code
90001
90001
90001
90001

### Remove Practice Location Confirmation



Do you really want to remove the following practice location?

Dakota Health System  
123 Main St  
Los Angeles, CA 90001



By removing this practice location, you will no longer be able to prescribe ESAs for patients with cancer from this location.

Cancel

Remove Practice Location

Add Practice Location

F

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[ESA APPRISE Oncology Program Healthcare Provider » Edit Profile](#)

## Edit Profile

### Prescriber Information

**First Name**

**Last Name**

**Professional Designation**

**Title**

**Email Address**

**Confirm Email Address**

**Phone (###-###-####)**

**Fax (###-###-####)**

**NPI #**

**- or -**

**State/Territory License #  
and Issuing State**

Cancel

Update Profile

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[ESA APPRISE Oncology Program Healthcare Provider » Change Password](#)

## Change Password

**New Password**

**Confirm New Password**

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## ESA APPRISE Oncology Program Hospital Designee

### [Hospital HCP Enrollment Management Report](#)

Manage your prescribers for this location.

### [Edit Profile](#)

Keep your profile updated.

### [Change Password](#)

Change your password.

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[ESA APPRISE Oncology Program Hospital Designee](#) » **Hospital HCP Enrollment Management Report**

## Hospital HCP Enrollment Management Report

### Affiliate Dashboard

Enrollment ID 	First Name	Last Name	Designation	Completed Date
548789	John	Smith	MD	01/24/2010
563482	Jane	Wintersmith	MD	03/03/2010
457687	Allison	Tennant	MD	03/30/2010

[Add Provider](#)

[Remove Provider](#)

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## Hospital HCP Enrollment Management Report

### Affiliate Dashboard

Enrollment ID	
548789	John
563482	Jane
457687	Allison

### Affiliated Provider Management



To add a provider to this site, enter the provider's Enrollment ID in the following field.

**Enrollment ID**

Cancel

Add Provider

Date
/24/2010
/03/2010
/30/2010

Add Provider

Remove Provider

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## Hospital HCP Enrollment

Affiliate Dashboard	
Enrollment ID	Name
548789	John
563482	Jane
457687	Allison

Date
/24/2010
/03/2010
/30/2010

### Affiliated Provider Management



Do you really want to remove the following provider?

John Smith  
Enrollment ID: 548789



By removing this provider, this individual will no longer have access to ESAs for patients with cancer at this location.

Cancel

Remove Provider

Add Provider

Remove Provider

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[ESA APPRISE Oncology Program Hospital Designee](#) » [Edit Profile](#)

## Edit Profile

### Authorized Hospital Designee Information

**First Name**

**Last Name**

**Title**

**Email Address**

**Confirm Email Address**

**Phone (###-###-####)**

**Fax (###-###-####)**

**Hospital Summary Report Opt-in**

Please send an email notification to the hospital email address listed above that summarizes all HCPs enrolled in the ESA APPRISE Oncology Program at the hospital each time a new HCP affiliated with the hospital enrolls in the Program. Note: You will automatically be notified when an affiliated HCP is removed from the ESA APPRISE Oncology Program, regardless of reason or cause.

[Cancel](#)

[Update Profile](#)

### Hospital HCP Enrollment Management Report Access

Manage a username and password to provide read-only access to the Hospital HCP Enrollment Management Report for individuals within the hospital.

**Hospital Username**

**Password**

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## Change Password

**New Password**

**Confirm New Password**

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## Hospital HCP Management Report

### Hospital Information

*HOSPITAL ADDRESS*  
Dakota Health System  
123 Main St  
Los Angeles, CA 90001

### Hospital HCP Management Report

Enrollment ID	First Name	Last Name	Designation	Completed Date
548789	John	Smith	MD	01/24/2010
563482	Jane	Wintersmith	MD	03/03/2010
457687	Allison	Tennant	MD	03/30/2010

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## Frequently Asked Questions (FAQs)

### Questions

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[Can patients still receive their ESAs if there is no enrolled provider on site on the actual day of injection?](#)

[When I treat a patient with cancer, do I need to send the completed Acknowledgment Form to the ESA APPRISE Oncology Program Call Center?](#)

### Answers

#### What is a REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a program established under the Food and Drug Administration Amendments Act (FDAAA) of 2007. FDAAA grants the FDA the authority to require a drug manufacturer to develop and implement a REMS if the FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks. This provision took effect on March 25, 2008. Links to approved REMS can be found on the FDA website at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>.

The FDA has determined that a REMS is necessary for the following marketed erythropoiesis stimulating agents (ESAs): Aranesp®, Epogen® and Procrit®.

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#### Who must enroll in the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program?

All healthcare providers (HCPs), inclusive of licensed non-physicians who prescribe, or prescribe and dispense, ESAs to treat patients with cancer for their anemia must enroll in the ESA APPRISE Oncology Program.

In addition to HCPs, for each hospital that dispenses an ESA for patients with cancer, a Hospital Designee, eg, Pharmacy Director or other Hospital Designee, must enroll in the ESA APPRISE Oncology Program.

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#### Is re-enrollment required?

No. The ESA APPRISE Oncology Program has been modified to eliminate the re-enrollment requirement for Healthcare Providers and Hospital Designees. Access to ESAs will not be impacted as long as the ESA APPRISE Oncology Program requirements continue to be met.

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#### I enrolled in the ESA APPRISE Oncology Program through my office, but now I want to initiate a new course of ESA therapy to a patient in the hospital. Do I have to re-enroll?

No, a single enrollment will apply across all your practice locations.

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#### As a nephrologist treating patients with ESAs for the anemia of Chronic Kidney Disease (CKD) who may also have cancer or are cancer survivors, do I need to enroll in the ESA APPRISE Oncology Program?

No, the ESA APPRISE Oncology Program is required for HCPs prescribing ESAs for the anemia resulting from cancer chemotherapy.

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#### I am a healthcare provider treating a patient who has cancer or is a cancer survivor but is now being treated with an ESA for anemia for non-oncology indications. Should this patient be subject to the ESA APPRISE Oncology Program requirements?

No, these patients are not subject to the ESA APPRISE Oncology Program.

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#### What are the consequences of not training and enrolling in the ESA APPRISE Oncology Program?

Failure to comply with Program requirements, including training and enrollment, will result in suspension of access to ESAs.

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#### How long will this enrollment take and can my nurse or office manager enroll for me?

The training and enrollment should take approximately 10-15 minutes to complete and can be completed on this website or facilitated by field-based company representatives. The ESA APPRISE Oncology Program requires that the actual prescribing HCP complete the training and enrollment in the Program.

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#### Do I have to counsel the patient on the benefits and risks of ESAs? If yes, what do I use to counsel the patient?

Yes. As a requirement of the ESA APPRISE Oncology Program, patients must be counseled on the benefits and risks of ESAs before each new course of therapy. The ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) must be used to counsel the patient and provide documentation of the discussion.

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#### How often do I need to provide a Medication Guide to a patient?

The Medication Guide is no longer a part of the REMS. It remains a part of the approved product label. Provide the Medication Guide to each patient at the initiation of each new course of ESA therapy and when it is materially revised or updated.

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#### We utilize standard forms for documenting patient consent. Can we modify our existing consent form to be like the Acknowledgment Form you provided?

The Program requires the risk:benefit discussion be documented using the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form).

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 which can be found under the Forms & Resources tab.

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#### Can the discussion with the patient on ESA risks and benefits be conducted by a nurse or other qualified healthcare provider?

This Program specifically requires that healthcare providers who prescribe, or prescribe and dispense, ESAs conduct and document the ESA risk:benefit discussion. However, nurses and other qualified healthcare providers may still be involved in their standard patient education processes.

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#### Can patients still receive their ESAs if there is no enrolled provider on site on the actual day of injection?

Yes, as long as the patient receiving the ESA had the risk:benefit discussion and signed the Acknowledgment Form with the trained and enrolled provider of the ESA prior to receiving the injection.

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#### When I treat a patient with cancer, do I need to send the completed Acknowledgment Form to the ESA APPRISE Oncology Program Call Center?

No. In private practice-based clinics, store the Acknowledgment Form(s) on-site and/or archive them through an electronic medical record system as long as they are retrievable. In hospitals, provide the completed Acknowledgment Form to the Hospital Designee responsible for maintaining and storing the forms.

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## Contact Us

For questions on the ESA APPRISE Oncology Program contact the ESA APPRISE Oncology Program Call Center at 1-866-284-8089, Monday through Friday between the hours of 8:00 AM to 8:00 PM (ET). You may also contact your local Amgen or Janssen Products, LP Field Representative for further assistance.

If you enroll via the paper ESA APPRISE Oncology Program Enrollment Form, the completed form can be faxed to 1-866-553-8124.

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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.



<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.

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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®.





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

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

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

**AMGEN**<sup>®</sup>  
Oncology



Assisting **P**roviders and cancer **P**atients with  
**R**isk **I**nformation for the **S**afe use of **E**SAs

# 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

and Mitigation Strategy (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<sup>®</sup>, Epogen<sup>®</sup>, and Procrit<sup>®</sup> prescribing information, including **Boxed WARNINGS** and Medication Guides available at [www.esa-apprise.com](http://www.esa-apprise.com).

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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>				
Study 1 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
Study 2 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
Study 3 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
Study 4 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>				
Study 5 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
Study 6 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>				
Study 7 Non-small cell lung cancer (n = 70)	12–14 g/dL	Not available	Quality of life	Decreased overall survival
Study 8 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<sup>®</sup>, Epogen<sup>®</sup> and Procrit<sup>®</sup> 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



Assisting Providers and cancer Patients with  
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# Section 3

## Program Requirements and Materials for Healthcare Providers

### HCP requirements for patient counseling

The ESA APPRISE Oncology Program requires HCPs to counsel patients in the following manner:

- 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 Acknowledgment Form.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form with each patient and providing each patient a copy of the signed form.
  - Completed Acknowledgment Forms (or modified version consistent with the allowable changes) must be available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record.
  - In a private practice-based clinic, store the forms on-site and/or archive them through an electronic medical records system as long as they are retrievable.
  - In a hospital, provide the completed Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms.

The form is titled "ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)". It includes instructions for healthcare providers, a patient acknowledgment section, and a written permission to share information section. The patient acknowledgment section includes a risk/benefit discussion and a signature line for the patient. The written permission section includes a signature line for the healthcare provider and a date field.

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# 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**

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.

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## 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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Assisting Providers and cancer Patients with  
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# SECTION 4

## HEALTHCARE PROVIDER ENROLLMENT



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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® (darbapoetin alfa), Epogen® (epoetin alfa) and Procrit® (epoetin alfa) are Erythropoiesis Stimulating Agents (ESAs) used for patients with cancer.

To become certified, healthcare providers (HCP) 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 1 866 553 824

**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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Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs  
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## Follow these 3 steps to enroll and participate in the ESA\* APPRISE Oncology Program:

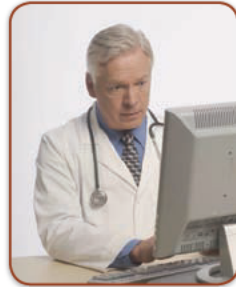
Failure to comply with the ESA APPRISE Oncology Program requirements will result in suspension of your access to ESAs (Aranesp® and Epogen®/Procrit®).



1

### Train

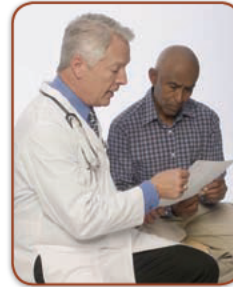
Complete the ESA APPRISE Oncology Program training, which includes a review of the risks of ESA therapy and appropriate use of ESAs for patients with cancer.



2

### Enroll

Enroll in the ESA APPRISE Oncology Program by completing the ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers.



3

### Counsel and Document

Prior to each new course of ESA therapy:

- Counsel each patient on the risks of ESAs using the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)<sup>†</sup>. Review ESA risk:benefit information with each patient and answer any questions they may have.
- Document that the ESA risk:benefit discussion occurred using the Acknowledgment Form. Complete each section of the Acknowledgment Form with each patient and provide each patient a copy of the signed form.
- Make completed Acknowledgment Forms available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not disclose patients' medical records.
- In a private practice-based clinic, store and archive the forms so that they are retrievable, whether physically on-site or electronically.
- In a hospital, provide the completed form to the Hospital Designee responsible for maintaining and storing the forms.

To train and enroll, contact your local Amgen or Janssen Products, LP Field Representative or access the ESA APPRISE Oncology Program website at [www.esa-apprise.com](http://www.esa-apprise.com). If you are unable to enroll via a Field Representative or online, please call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 for further assistance.

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).

\*ESA = erythropoiesis stimulating agent [Aranesp® (darbepoetin alfa)/Epogen® (epoetin alfa)/Procrit® (epoetin alfa)].

<sup>†</sup>Or modified version consistent with allowable changes.

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Reference ID: 3428792



# 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

- 1 Counsel the patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
- 2 Complete each section of the form as required with the patient.
- 3 Provide a copy of the signed form to the patient.
- 4 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.

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

To become certified, Hospital Designees must train and enroll into the ESA APPRISE Oncology Program:

- Complete the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- Complete the 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 access to ESAs for the hospital for which you are responsible.

By completing enrollment, I agree to the following on behalf of the hospital for which I am responsible:

- I have been designated by hospital management to assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in the hospital listed below.
- I have completed the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- I understand that if healthcare providers (HCPs) in the hospital prescribe Aranesp® or Epogen®/Procrit® to patients with cancer, failure of the staff to comply with enrollment requirements will lead to suspension of access to Aranesp® and Epogen®/Procrit® for the hospital.
- I will inform all HCPs who prescribe Aranesp® or Epogen®/Procrit® for patients with cancer at the hospital of the ESA APPRISE Oncology Program training and certification requirements.
- I will establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program, such that:
  - Aranesp® or Epogen®/Procrit® is only dispensed to patients with cancer after verifying:
    - that the HCP who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is certified in the ESA APPRISE Oncology Program; and
    - that the discussion between the patient and the Program-certified provider on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and provider signatures on the ESA APPRISE Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) prior to initiation of each new course of Aranesp® or Epogen®/Procrit® therapy.
  - If an HCP who prescribes Aranesp® or Epogen®/Procrit® is not certified in the ESA APPRISE Oncology Program, the provider will be notified that they are not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
- I am authorized to oversee compliance with Program auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
- I will maintain evidence of compliance with the ESA APPRISE Oncology Program for auditing purposes, as follows:
  - Documentation (ie, unique enrollment ID number) that each HCP in the hospital who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is certified in the Program.
  - Documentation of the risk:benefit discussion between certified provider and patient on the Acknowledgment Form for each patient with cancer for whom an Aranesp® or Epogen®/Procrit® prescription was filled; the Acknowledgment Forms are to be stored on-site and/or archived in a retrievable manner.

## Hospital Designee Information

Authorized Hospital Designee name \_\_\_\_\_ Title \_\_\_\_\_

Authorized Hospital Designee signature \_\_\_\_\_ Date \_\_\_\_\_

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

Email \_\_\_\_\_



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



## Hospital Enrollment Information

Hospital name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_

HIN# \_\_\_\_\_ and/or Customer ID Type and # \_\_\_\_\_

## Hospital Contact Information for Receipt of Program Materials (if different from authorized designee)

Name \_\_\_\_\_

same as address listed above

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_

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

An ESA APPRISE Oncology Program enrollment confirmation and an identification number will be sent via email (or by fax if no email address is provided) to each individual listed above within 1 business day of receipt of this completed form. This confirmation email will also include instructions on how to access a report of HCPs at your hospital who are certified in the Program. Upon 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 the address provided above.

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.



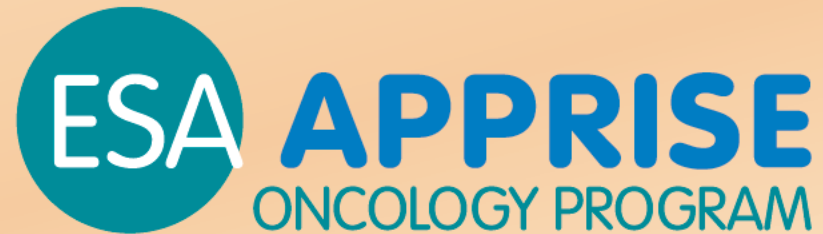


**Aranesp**<sup>®</sup>  
(darbepoetin alfa)

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

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

**AMGEN**  
Oncology



Assisting **P**roviders and cancer **P**atients with  
**R**isk **I**nformation for the **S**afe use of **E**SAs

# Training Module for Hospital Designees



# Training Module for Hospital Designees

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 Hospital Designees at hospitals that 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 the hospital's access to ESAs**

This training module, as a component of this REMS Program, presents the requirements for healthcare providers (HCPs) who prescribe, or prescribe and dispense, Aranesp®, Epogen®, or Procrit® for patients with cancer as well as the requirements for Hospital Designees who must oversee implementation of this safety program at their respective Hospitals.

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

and Mitigation Strategy (REMS) for Aranesp®, Epogen®, and Procrit®.

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# Training Module for Hospital Designees

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 and Hospital Designee Program requirements and materials**

**Section 4: Enrollment**

Please see the Aranesp<sup>®</sup>, Epogen<sup>®</sup>, and Procrit<sup>®</sup> 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  
Risk Information for the Safe use of ESAs



# 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>				
Study 1 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
Study 2 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
Study 3 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
Study 4 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>				
Study 5 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
Study 6 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>				
Study 7 Non-small cell lung cancer (n = 70)	12–14 g/dL	Not available	Quality of life	Decreased overall survival
Study 8 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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Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs



# 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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Assisting Providers and cancer Patients with  
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## Section 2

# Hospital Designee 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 Hospital Designee 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  
AND HOSPITAL DESIGNEES



Assisting Providers and cancer Patients with  
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## Section 3

# Program Requirements and Materials for Healthcare Providers and Hospital Designees

### Hospital Designee Requirements

- Assume the authority and responsibility to internally coordinate and oversee implementation of the ESA APPRISE Oncology Program requirements in the hospital(s) for which you are responsible.
- Complete the Training Module for Hospital Designees.
- Understand that if HCPs in the hospital prescribe Aranesp® or Epogen®/Procrit® to patients with cancer, failure to comply with Program requirements will lead to suspension of access to ESAs for the hospital.
- Inform all HCPs who prescribe Aranesp® or Epogen®/Procrit® for patients with cancer at the hospital of the Program training and certification requirements.
- Establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the ESA APPRISE Oncology Program, such that:
  - ESAs are only dispensed to patients with cancer after verifying:
    - that the HCP who prescribes ESAs for patients with cancer is certified in the Program; and
    - that the discussion between the patient and the Program-certified provider on the risks of ESA therapy is documented by patient and provider signatures on the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) prior to initiation of each new course of ESA therapy.
  - If an HCP who prescribes ESAs is not certified in the ESA APPRISE Oncology Program, the provider will be notified that they are not able to prescribe ESAs for patients with cancer.

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# Section 3

## Program Requirements and Materials for Healthcare Providers and Hospital Designees

- 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**

**Instructions for Healthcare Providers**

- 1. Complete the form for each patient receiving ESA therapy.
- 2. Complete a copy of the form for each patient receiving ESA therapy.
- 3. Complete a copy of the form for each patient receiving ESA therapy.

**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.

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ESA APPRISE ONCOLOGY PROGRAM  
Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs

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## Section 3

# Program Requirements and Materials for Healthcare Providers and Hospital Designees

- Oversee compliance with Program auditing to assess the effectiveness of the Program.
- Maintain evidence of compliance with the Program for auditing purposes, as follows:
  - Documentation (ie, unique enrollment ID number) that each HCP in the hospital who prescribes ESAs for patients with cancer is certified in the Program.
  - Documentation of the risk:benefit discussion between certified provider and patient on the Acknowledgment Form for each patient with cancer for whom an Aranesp® or Epogen®/Procrit® prescription was filled; the Acknowledgment Forms are to be stored on-site and/or archived in a retrievable manner.
    - Completed Acknowledgment Forms (or modified version consistent with the allowable changes) must be available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record.

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 3

## Program Requirements and Materials for Healthcare Providers and Hospital Designees

**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 (and an alternate contact, if provided) will receive an email (or fax if no email address is provided) with the ESA APPRISE Oncology Program enrollment ID number unique to the hospital. This enrollment ID number allows you to identify HCPs enrolled at your location, by clicking “Login” at the top right of the ESA APPRISE Oncology Program website home page. You can also order more Program materials via [www.esa-apprise.com](http://www.esa-apprise.com) using the hospital enrollment ID number.

Once you have enrolled, you will receive the following materials to assist HCPs in the hospital in implementing the Program:

- 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 to Patients With Cancer
- Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to 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.

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

and Mitigation Strategy (REMS) for Aranesp®, Epogen®, and Procrit®.

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# SECTION 4

## HOSPITAL DESIGNEE ENROLLMENT



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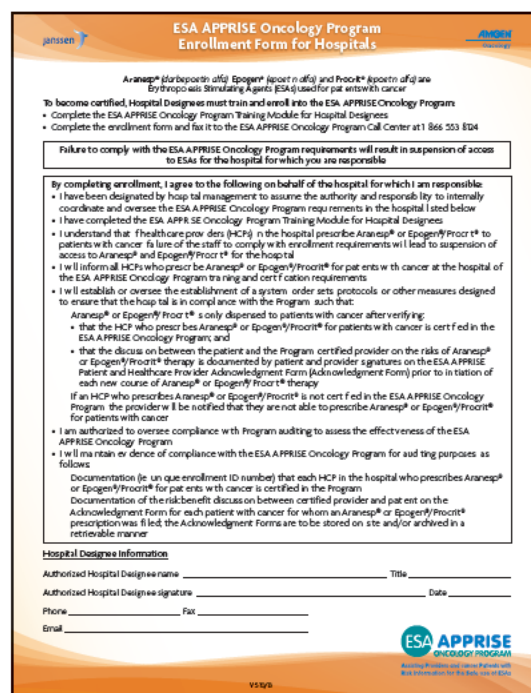


# Section 4

## Hospital Designee 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, and commits you to complying with the Program requirements.

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 Hospitals". The form includes the following sections:

- Header:** Janssen logo, "ESA APPRISE Oncology Program Enrollment Form for Hospitals", and Amgen logo.
- Introduction:** States that Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa) are Erythropoiesis Stimulating Agents (ESAs) used for patients with cancer. It notes that to become certified, Hospital Designees must train and enroll into the ESA APPRISE Oncology Program.
- Requirements:** Lists two main requirements: "Complete the ESA APPRISE Oncology Program Training Module for Hospital Designees" and "Complete the enrollment form and fax it to the ESA APPRISE Oncology Program Call Center at 1 866 553 8344".
- Warning:** A box states: "Failure to comply with the ESA APPRISE Oncology Program requirements will result in suspension of access to ESAs for the hospital for which you are responsible".
- Agreement:** A section titled "By completing enrollment, I agree to the following on behalf of the hospital for which I am responsible:" containing several bullet points:
  - I have been designated by hospital management to assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in the hospital listed below.
  - I have completed the ESA APPRISE Oncology Program Training Module for Hospital Designees.
  - I understand that if health care providers (HCPs) in the hospital prescribe Aranesp® or Epogen®/Procrit® to patients with cancer, failure of the staff to comply with enrollment requirements will lead to suspension of access to Aranesp® and Epogen®/Procrit® for the hospital.
  - I will inform all HCPs who prescribe Aranesp® or Epogen®/Procrit® for patients with cancer at the hospital of the ESA APPRISE Oncology Program training and certification requirements.
  - I will establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program, such that:
    - Aranesp® or Epogen®/Procrit® is only dispensed to patients with cancer after verifying:
      - that the HCP who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is certified in the ESA APPRISE Oncology Program; and
      - that the discussion between the patient and the Program certified provider on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and provider signatures on the ESA APPRISE Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) prior to initiation of each new course of Aranesp® or Epogen®/Procrit® therapy.
  - If an HCP who prescribes Aranesp® or Epogen®/Procrit® is not certified in the ESA APPRISE Oncology Program, the provider will be notified that they are not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
  - I am authorized to oversee compliance with Program auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
  - I will maintain evidence of compliance with the ESA APPRISE Oncology Program for auditing purposes as follows:
    - Documentation (ie, unique enrollment ID number) that each HCP in the hospital who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is certified in the Program.
    - Documentation of the risk/benefit discussion between certified provider and patient on the Acknowledgment Form for each patient with cancer for whom an Aranesp® or Epogen®/Procrit® prescription was filled; the Acknowledgment Forms are to be stored on site and/or archived in a retrievable manner.

- Hospital Designee Information:** Fields for Authorized Hospital Designee name, Title, Authorized Hospital Designee signature, Date, Phone, Fax, and Email.
- Footer:** ESA APPRISE ONCOLOGY PROGRAM logo and the text "Assisting Providers and Cancer Patients with Risk Information for the Safe Use of ESAs".

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Failure to comply with the ESA\* APPRISE Oncology Program requirements will result in suspension of access to ESAs (Aranesp® and Epogen®/Procrit®) at the hospital(s) for which you are responsible.



## 1 Select a Hospital Designee

This individual is designated by hospital management to assume authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program in the hospital (eg, Pharmacy Director, Head of Hematology/Oncology Department).



## 2 Complete Training

The Hospital Designee must complete the ESA APPRISE Oncology Program training for Hospital Designees.



## 3 Enroll

The Hospital Designee must enroll in the ESA APPRISE Oncology Program by completing the ESA APPRISE Oncology Program Enrollment Form for Hospitals.



## 4 Implement

The Hospital Designee must establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that ESAs are only dispensed to patients with cancer after verifying:

- that the healthcare provider (HCP) who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is certified in the ESA APPRISE Oncology Program.
  - if an HCP who prescribes Aranesp® or Epogen®/Procrit® is not certified in the ESA APPRISE Oncology Program, the provider will be notified that he/she is not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
- that the discussion between the patient and ESA APPRISE Oncology Program-certified provider on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and provider signatures on the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) prior to initiation of each new course of Aranesp® or Epogen®/Procrit® therapy.

To train and enroll, contact your local Amgen or Janssen Products, LP Field Representative or access the ESA APPRISE Oncology Program Website at [www.esa-apprise.com](http://www.esa-apprise.com). If you are unable to enroll via a field representative or online, please call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089 for further assistance.

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).

\*ESA = erythropoiesis stimulating agent [Aranesp® (darbepoetin alfa)/Epogen® (epoetin alfa)/Procrit® (epoetin alfa)].

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Reference: Epogen® and Procrit®.



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

**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 (ESA\*) 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-oculated information)  
 Site ID \_\_\_\_\_  
 Site Name \_\_\_\_\_  
 Site Address (Address City State Zip) \_\_\_\_\_

\*Aranesp® and Epogen®/Procrit® are off-injectable drugs with distinct dosage schedules. IDr 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/ 3

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



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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ANN T FARRELL  
12/31/2013