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 Epogen/Procrit for patients with cancer.

- informing patients about the risk of shortened overall survival and/or increased risk of tumor progression or recurrence when Epogen/Procrit 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**\(^2\) **and dispense**\(^3\) **Epogen/Procrit for patients with cancer in private practice settings and healthcare providers who prescribe Epogen/Procrit for patients with cancer in hospitals are specially certified.**

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\(^1\) Amgen Inc. is the licensee under BL 103234. Although Amgen and Janssen have a contractual agreement under which Janssen is to carry out the responsibilities under the REMS for Procrit on behalf of Amgen, Amgen retains primary responsibility for all actions described in the REMS.

\(^2\) For the purposes of this REMS, the terms prescribe and prescription include medication orders in the clinic or hospital settings.

\(^3\) 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.
a. Amgen will ensure that HCPs who both prescribe and dispense Epogen/Procrit for patients with cancer in private practice settings and HCPs who prescribe Epogen/Procrit 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.

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, Epogen/Procrit 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 Epogen/Procrit 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 Epogen/Procrit for patients with cancer are specially certified.

a. Amgen will ensure that hospitals that dispense Epogen/Procrit 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) Epogen/Procrit is only dispensed to patients with cancer after verifying:
   a) that the healthcare provider who prescribed Epogen/Procrit 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 Epogen/Procrit 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 Epogen/Procrit therapy.

2) If an HCP that prescribes Epogen/Procrit is not certified in the ESA APPRISE Oncology Program, the provider will be notified that they are not able to prescribe Epogen/Procrit 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 Epogen/Procrit 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 Epogen/Procrit 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 Epogen/Procrit 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 Epogen/Procrit 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. **Epogen/Procrit 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 Epogen/Procrit 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 Epogen/Procrit 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 Epogen/Procrit 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.
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.

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.

Sincerely,

Amgen
Janssen Products, LP

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

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

This document has been required by the US Food and Drug Administration as part of a Risk Evaluation and Mitigation Strategy (REMS) for Aranesp®, Epogen®, and Procrit®.
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-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 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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Sincerely,

Amgen
Janssen Products, LP

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

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

This document has been required by the US Food and Drug Administration as part of a Risk Evaluation and Mitigation Strategy (REMS) for Aranesp®, Epogen®, and Procrit®.
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.

Key Program Requirements

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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

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®.

Reference ID: 3429800
Welcome to the ESA APPRISE Oncology Program

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.

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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 1-866-284-8039, or
- Contact your local Amgen or Janssen Products, LP Field Representative

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Reference ID: 3429800
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:
  
  o educating healthcare providers about the risks and safe use conditions of Aranesp® (darbepoetin alfa) and Epogen®/Procrit® (epoetin alfa) for patients with cancer.
  o informing patients about the risks of shortened overall survival and/or increased risk of tumor progression or recurrence when Aranesp® or Epogen®/Procrit® 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:
  
  o Do not fax or mail a copy of the Acknowledgment Form to the ESA APPRISE Oncology Program Call Center.
  o 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.
  o 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.
  o 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:
  
  o 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.
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.

- 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.
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.
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.
Welcome to the ESA APPRISE Oncology Program

Begin Training & Enrollment

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

- Yes
- No

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.

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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

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

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Reference: 3429800
Welcome to the ESA APPRISE Oncology Program

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 HCP: 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.

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Welcome to the ESA APPRISE Oncology Program

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.

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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.

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

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Click the next button to continue
ESAs resulted in decreased logocerebral control/progression-free survival and overall survival.

As shown in the upper box, those who received ESAs were at increased risk of study-related deaths and in patients with advanced breast and non-small cell lung cancer requiring radiation therapy (studies 6 and 8). In patients receiving chemotherapy for metastatic breast cancer (study 7) or lymphoma (eligibility study 8), and in patients with non-small cell lung cancer or various malignancies who were not receiving chemotherapy or radiation therapy (studies 7 and 8).

Dose (mg/kg) per week

12.5 mg/kg (n = 88)

10.0 mg/kg (n = 88)

7.5 mg/kg (n = 88)

5.0 mg/kg (n = 88)

5.0 mg/kg

2.5 mg/kg

1.25 mg/kg

10 mg/kg

12.5 mg/kg

15 mg/kg

17.5 mg/kg

20 mg/kg

25 mg/kg

12.5 mg/kg

10 mg/kg

7.5 mg/kg

5 mg/kg

2.5 mg/kg

1.25 mg/kg

10 mg/kg

Dose-adjusted progression-free survival and Overall Survival

Study 1 was a randomized, open-label, controlled factorial design study in which dacarbazine was administered to prevent all 735 patients were randomized to receive adjuvant breast cancer therapy. A final analysis was performed after a median follow-up of approximately 3.5 years. The median survival time was lower (0.6 years, 0.95 vs. 0.95 vs. 0.95 vs. 0.95) and the 3-year progression-free survival rate was lower (72, 0.7, 0.6, 0.6, 0.6, 0.6, 0.6, 0.6, 0.6, 0.6, 0.6). Dacarbazine was administered as a 4- to 6-week treatment initiated at a dose of 150 mg/m². Study 2 was a randomized, double-blind study (dacarbazine vs. placebo) performed in 364 patients with metastatic melanoma receiving chemotherapy. Dacarbazine was administered as a 4- to 6-week treatment initiated at a dose of 150 mg/m². Study 3 was a randomized, double-blind study (dacarbazine vs. placebo) performed in 480 patients with advanced malignancies. Dacarbazine was administered as an 8- to 12-week treatment initiated at a dose of 150 mg/m². Overall survival was significantly shorter in patients receiving dacarbazine (HR 1.02, 95% CI 1.01, 1.03, 0.04 vs. 0.02).

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.
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.

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.

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

Important Dosing and Treatment:
- Initiate ESAs in patients on the basis of an absolute transfusion requirement.
- Use the lowest dose of ESA that results in control of anemia.
- Discontinue ESAs following resolution of anemia.

Please see the Aranesp®, Epogen®, and Procrit® Medication Guides.

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

**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]

---

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

---

Training & Enrollment Progress:

BACK  |  PROGRESS  |  NEXT
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 as a substitute for RBC transfusions.
- ESAs have not been shown to improve overall survival.

Important Dosing and Treatment Considerations:
- Initiate ESAs in patients with cancer with anemia only if symptoms are present.
- Use the lowest dose of ESA to achieve a target hematocrit of 30%.
- Discontinue ESAs following clinical improvement.

Please see the Aranesp® and Epogen® prescribing information for complete information. Alternatively, please use the link to view the Medialication 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

Training & Enrollment Progress
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 as a substitute for RBC transfusions.
  - ESAs have not been shown to prolong survival.

Important Dosing and Treatment Guidance

- Initiate ESAs in patients on Day 1 of chemotherapy
- Use the lowest dose of ESA that achieves a hemoglobin of 11 g/dL
- Discontinue ESAs following completion of chemotherapy

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- 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 as a substitute for RBC transfusions.
- ESAs have not been shown to:

Important Dosing and Treatment

- Initiate ESAs in patients who have not responded to RBC transfusions in the last 4 weeks.
- Use the lowest dose of ESA to achieve a hemoglobin of 10 to 12 g/dL.
- Discontinue ESAs following cancer remission.

Please see the Aranesp®, Epogen® and Procrit® Patient Mediation 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.

---

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

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

[True] [False]

---

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

Important Dosing and Treatment Considerations
- Initiate ESAs in patients with cancer receiving myelosuppressive chemotherapy at a dose that results in a corrected hemoglobin level of less than 10 g/dL.
- Use the lowest dose of ESA that results in a corrected hemoglobin level of 10 to 12 g/dL.
- Discontinue ESAs following completion of chemotherapy.

Please see the Aranesp®, Epopen®, and Procrit® Medication Guides.

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

Aranesp® and Epopen®/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
Click here to proceed to Knowledge Check
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 as a substitute for RBC transfusions.
  - ESAs have not been shown to be effective in patients with chronic kidney disease.

Important Dosing and Treatment
- Initiate ESAs in patients demonstrating severe anemia (< 9 g/dL).
- Use the lowest dose of ESA that results in the maximum increase in hemoglobin level.
- Discontinue ESAs following remission or resolution of anemia.

Please see the Aranesp®, Epogen®, and Procrit® Patient Medication Guides.

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

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
Click here to proceed to Knowledge Check
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 as a substitute for RBC transfusions.
  - ESAs have not been shown to improve survival or other measures of clinical outcomes in patients with cancer.

Important Dosing and Treatment Recommendations

- Initiate ESAs in patients with cancer only after RBC transfusions are no longer required.
- Use the lowest dose of ESA that results in a maximum hemoglobin increase of 1.0 g/dL.
- Discontinue ESAs followin...
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 as a substitute for RBC transfusions.
- ESAs have not been shown...

Important Dosing and Treatment
- Initiate ESAs in patients on the lowest efficacious dose of a chemotherapy regimen.
- Use the lowest dose of ESAs that will achieve the desired hemoglobin level.
- Discontinue ESAs following the completion of chemotherapy.

Please see the Aranesp®, Epogen®, and Procrit® product literature for a full list of contra-indications, precautions, and warnings. Full prescribing information, including Boxed WARNINGS and 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.

---

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

Important Dosing and Treatment
- Initiate ESAs in patients on the lowest effective dose that achieves the target hemoglobin.
- Use the lowest dose of ESA that achieves the target hemoglobin.
- Discontinue ESAs following completion of chemotherapy.

Please see the Aranesp®, Epogen®, and Procrit® 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
Click here to proceed to Knowledge Check
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.
- 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.

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 1-866-384-0809 or ask your local Amgen or Janssen Products, LP Field Representative.

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

Aranesp® and 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
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**

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

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
I agree to the following:

- 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 of 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.

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 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 patients medical record; and to store the Acknowledgment Forms on-site and/or archive them in a retrievable manner.
- I will ensure that the ESA obtained for use in my patients with cancer will not be prescribed, or prescribed and dispensed, by an uncertified HCP.
- 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.

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

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 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.
ESA APPRISE Oncology Program Enrollment for Healthcare Providers

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

- Primary Practice Location

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

<table>
<thead>
<tr>
<th>ZIP</th>
<th>City</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Please select your Primary Practice Location

Primary Practice Search Results

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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

Training & Enrollment Progress

BACK NEXT
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
  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
  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
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.

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<thead>
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<th>ZIP</th>
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<th>State</th>
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</thead>
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Please select up to 10 Secondary Practice Locations

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<th>State</th>
<th>ZIP Code</th>
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<tbody>
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<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Training & Enrollment Progress

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ESA APPRISE Oncology Program Enrollment for Healthcare Providers

Thank you for participating in the ESA APPRISE Oncology Program

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)

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<tr>
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<th>Site Address</th>
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<td>85225</td>
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<td>Scottsdale</td>
<td>AZ</td>
<td>85225</td>
<td>Secondary</td>
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</tbody>
</table>

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.
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.

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.

Click the next button to continue

Training & Enrollment Progress

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Section 1: Key Safety Information for Use of ESAs in Patients With Cancer

ESAs resulted in decreased locoregional control/progression-free survival and 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) or patients receiving chemotherapy for metastatic breast cancer (Study 1) or lymphoma therapy (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).

<table>
<thead>
<tr>
<th>Study Reference</th>
<th>Treatment Details</th>
<th>Follow-Up</th>
<th>Efficacy Outcomes</th>
<th>Result</th>
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</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>Metastatic breast cancer</td>
<td>12.0 mg/kg, 12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
</tr>
<tr>
<td>Study 2</td>
<td>Lymphoma therapy</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
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<td>Study 3</td>
<td>Head and neck cancer</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
</tr>
<tr>
<td>Study 4</td>
<td>Metastatic breast cancer</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
</tr>
<tr>
<td>Study 5</td>
<td>Metastatic lung cancer</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
</tr>
<tr>
<td>Study 6</td>
<td>Lymphoma therapy</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
</tr>
<tr>
<td>Study 7</td>
<td>Metastatic breast cancer</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
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<tr>
<td>Study 8</td>
<td>Metastatic lung cancer</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
<td>12.0 mg/kg, 12.1 mg/kg</td>
</tr>
</tbody>
</table>

Decreased Overall Survival

Study 1 was a randomized, placebo-controlled study of 393 women with metastatic breast cancer receiving chemotherapy, patients received either epoetin alfa or placebo up to 1 year. This study was designed to show that survival was superior in patients receiving epoetin alfa compared to placebo. However, the study indicated that survival was not significantly different between the two groups.

Study 2 was a randomized, double-blind study (dacetoprost vs. placebo) conducted in 344 patients with non-small-cell lung cancer receiving chemotherapy. The median follow-up was 26 months. The results showed that the survival rate was not significantly different between the two groups.

Study 3 was a randomized, double-blind study (dacetoprost vs. placebo) conducted in 344 patients with non-small-cell lung cancer receiving chemotherapy. The median follow-up was 26 months. The results showed that the survival rate was not significantly different between the two groups.

Study 4 was a randomized, double-blind study (dacetoprost vs. placebo) conducted in 344 patients with non-small-cell lung cancer receiving chemotherapy. The median follow-up was 26 months. The results showed that the survival rate was not significantly different between the two groups.

Study 5 was a randomized, double-blind study (dacetoprost vs. placebo) conducted in 344 patients with non-small-cell lung cancer receiving chemotherapy. The median follow-up was 26 months. The results showed that the survival rate was not significantly different between the two groups.

Study 6 was a randomized, double-blind study (dacetoprost vs. placebo) conducted in 344 patients with non-small-cell lung cancer receiving chemotherapy. The median follow-up was 26 months. The results showed that the survival rate was not significantly different between the two groups.

Study 7 was a randomized, double-blind study (dacetoprost vs. placebo) conducted in 344 patients with non-small-cell lung cancer receiving chemotherapy. The median follow-up was 26 months. The results showed that the survival rate was not significantly different between the two groups.

Study 8 was a randomized, double-blind study (dacetoprost vs. placebo) conducted in 344 patients with non-small-cell lung cancer receiving chemotherapy. The median follow-up was 26 months. The results showed that the survival rate was not significantly different between the two groups.

Decreased Progression-free Survival and Overall Survival

Study 1 was a randomized, open-label, controlled study in which patients with advanced breast cancer were randomized to receive epoetin alfa or placebo. The results showed that the progression-free survival rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 2 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the progression-free survival rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 3 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the progression-free survival rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 4 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the progression-free survival rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 5 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the progression-free survival rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 6 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the progression-free survival rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 7 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the progression-free survival rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 8 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the progression-free survival rate was significantly lower in the epoetin alfa group compared to the placebo group.

Decreased Locoregional Control

Study 1 was a randomized, open-label, controlled study in which patients with advanced breast cancer were randomized to receive epoetin alfa or placebo. The results showed that the local-regional control rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 2 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the local-regional control rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 3 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the local-regional control rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 4 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the local-regional control rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 5 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the local-regional control rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 6 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the local-regional control rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 7 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the local-regional control rate was significantly lower in the epoetin alfa group compared to the placebo group.

Study 8 was a randomized, open-label, controlled study in which patients with non-small-cell lung cancer were randomized to receive epoetin alfa or placebo. The results showed that the local-regional control rate was significantly lower in the epoetin alfa group compared to the placebo group.

Please see the full prescribing information for Aneopterin (dacetoprost sodium) for additional information.

FAQs

*Yes, I have reviewed all 6 of Section 1.*

Training & Development Progress

This research is supported by the National Institutes of Health (NIH). Learn more at https://www.nih.gov.
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.

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.

---

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

Training & Enrollment Progress
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 to be treated with agents known to cause anemia.
  - as a substitute for RBC transfusions.
- ESAs have not been shown to prevent the need for RBC transfusions, reduce complications associated with anemia, improve quality of life in patients with cancer, or increase survival.

Important Dosing and Treatment Considerations
- Initiate ESAs in patients only when anemia is present and the benefit of ESA treatment is expected to outweigh the risk of treatment.
- Use the lowest dose of ESA that will adequately correct anemia and maintain the Hb level at or above 11 g/dL, unless the patient is achieving a satisfactory clinical response with lower Hb levels.
- Discontinue ESAs following completion of chemotherapy unless the patient's anemia is expected to recur.

Please see the Aranesp® ESA Patient Medication Guide and Product Information for complete prescribing information.

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.

---

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

**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

**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

Training & Enrollment Progress:

BACK | PROGRESS | NEXT
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 as a substitute for RBC transfusion.

- ESAs have not been shown to prolong survival.

Important Dosing and Treatment

- Initiate ESAs in patients with anemia.
- Use the lowest dose of ESA to achieve and maintain a hemoglobin level of 11 g/dL.
- Discontinue ESAs following resolution of anemia.

Please see the Aranesp®, Epogen®, and Procrit® Patient 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.

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
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 not requiring transfusion as a substitute for RBCs
- ESAs have not been studied in:

Important Dosing and Treatment Considerations
- Initiate ESAs in patients with cancer at the lowest dose effective to reach an Hb level target of 11 to 12 g/dL.
- Use the lowest dose of ESA effective to achieve target Hb level.
- Discontinue ESAs following discontinuation of chemotherapy.

Please see the Aranesp®, Epogen® and Procrit® 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.

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
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 as a substitute for RBC transfusions.

- ESAs have not been shown to:

Important Dosing and Treatment:
- Initiate ESAs in patients whose hemoglobin levels are 10 g/dL or less.
- Use the lowest dose of ESA that results in an increase of 1 to 2 g/dL.
- Discontinue ESAs following RBC transfusion.

Please see the Aranesp®, Epogen®, and Procrit® Medication Guides.

Aranesp®, Epogen®, and Procrit® 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.

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

Training & Enrollment Progress:
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 as a substitute for RBC transfusions.
- ESAs have not been shown to benefit patients with anemia due to uremia.

Important Dosing and Treatment Considerations
- Initiate ESAs in patients on the initial dose.
- Use the lowest dose of ESA that will effectively increase hematocrit.
- Discontinue ESAs following successful chemotherapy and associated hematologic recovery.

Please see the Aranesp®, Epogen®, and Procrit® Information for Healthcare Providers and 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.

---

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
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 as a substitute for RBC transfusions.
- ESAs have not been shown to improve survival in patients with cancer.

Important Dosing and Treatment Considerations

- Initiate ESAs in patients only when hemoglobin level is less than 10 g/dL.
- Use the lowest dose of ESA that will achieve a hemoglobin level of 10 to 12 g/dL.
- Discontinue ESAs following RBC transfusions.

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?

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

Training & Enrollment Progress

Back Next
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 as a substitute for RBC transfusions.
- ESAs have not been shown to:

Important Dosing and Treatment Considerations

- Initiate ESAs in patients on appropriate dose of ESA.
- Use the lowest dose of ESA that will achieve the recommended target Hgb level.
- Discontinue ESAs following completion of chemotherapy.

Please see the Aranesp®, Epogen® and Procrit® Medication Guides.

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

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

**Hospital Designee Knowledge Check**

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

- [ ] True
- [ ] False

---

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

---

Training & Enrollment Progress
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 as a substitute for RBC transfusions.
  - ESAs have not been shown to improve overall survival.

Important Dosing and Treatment Considerations

- Initiate ESAs in patients on chemotherapy.
- Use the lowest dose of ESA that will maintain hemoglobin above 11.0 g/dL.
- Discontinue ESAs following the completion of chemotherapy courses.

Please see the Aranesp®, Epogen®, and Procrit® package inserts 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
Click here to proceed to Knowledge Check
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 as a substitute for RBC transfusion.
  - ESAs have not been shown to provide survival benefit.

Important Dosing and Treatment

- Initiate ESAs in patients of normal or near-normal body weight, if feasible.
- Use the lowest dose of ESA to achieve the desired improvement in hemoglobin level.
- Discontinue ESAs following completion of chemotherapy.

Please see the Aranesp®, Epogen®, and Procrit® Medication Guides for dosing and other important information.

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.

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
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 Anasert® or Eprex®/Procrit® before each new course of ESA therapy by reviewing the Acknowledgement 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 Acknowledgement Form with each patient and providing each patient a copy of the signed form.

- Completed Acknowledgement 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, complete the completed Acknowledgement 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 Anasert® or Eprex®/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 Anasert® or Eprex®/Procrit® for patients with cancer at the hospital of Program training and certification requirements.
- Establish or override 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 signatories on the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgement 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.
- Ensure compliance with Program auditing to assess the effectiveness of the Program.
- Maintain evidence of compliance with the Program for auditing purposes, as follows:
  - Documentation (e.g., unique enrollment ID number) that each HCP in the hospital who prescribed ESAs for patients with cancer is certified in the Program.
  - Documentation of the risk benefit discussion between certified provider and patient on the Acknowledgement Form for each patient with cancer for whom an Anasert® or Eprex®/Procrit® prescription was filled. The Acknowledgement Forms are to be stored on-site and/or archived in a retrievable manner.
  - Completed Acknowledgement 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 Acknowledgement Form, please refer to the Guidelines for Acknowledgement Form Integration Within Healthcare Systems and Clinics.

Please see the Anasert®, Eprex® 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 "Logon" at the top right of the ESA APPRISE Oncology Program website home page. You can also order more Program materials via www.esa-approse.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 Acknowledgement Forms
- Guidelines for Acknowledgement Form Integration Within Healthcare Systems and Clinics
- Steps for Healthcare Providers Who Prescribe, or Describe 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 1-866-264-0089 or ask your local Amgen or Janssen Product, LP Field Representative.

Anasert® and Procrit® are registered trademarks of Amgen Inc. Procrit® is a registered trademark at Janssen Products, LP. Anasert® and Eprex®/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 and Hospital Designees?

Yes, I have reviewed all of Section 3.
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

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

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
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 filed.

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
ESA APPRISE Oncology Program Enrollment for Hospitals

- Authorized Hospital Designee Information

  First Name
  Last Name
  Title
  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.

- 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 (mm/dd/yyyy)

Training & Enrollment Progress

BACK NEXT
ESA APPRISE Oncology Program Enrollment for Hospitals

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

ZIP City State

Search

Hospital Main Address Search Results

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>ZIP Code</th>
</tr>
</thead>
</table>

Hospital main address is not listed

Hospital Contact Information for Receipt of Program Materials

Click here if different from the authorized designee

Training & Enrollment Progress

BACK NEXT
ESA APPRISE Oncology Program Enrollment for Hospitals

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

Training & Enrollment Progress
ESA APRISE Oncology Program Enrollment for Hospitals

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

<table>
<thead>
<tr>
<th>ZIP</th>
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<th>State</th>
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<tbody>
<tr>
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<td></td>
</tr>
</tbody>
</table>

Search

Please select your hospital

Hospital Main Address Search Results

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>ZIP Code</th>
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</tr>
</tbody>
</table>

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 APRISE 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
ESA APPRISE Oncology Program Enrollment for Hospitals

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
- 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 is affiliated with the hospital enrolls in the Program.

Note: You will be automatically notified of all HCP enrollment terminations, whether voluntary or for cause.

- Click here if contact is the same as the authorized designee

Training & Enrollment Progress

BACK

NEXT
# ESA APPRISE Oncology Program Enrollment for Hospitals

## 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:

<table>
<thead>
<tr>
<th>New Hospital Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1001 Main Blvd</td>
</tr>
<tr>
<td>Los Angeles, CA 90001</td>
</tr>
</tbody>
</table>

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

---

Training & Enrollment Progress

[BACK] [NEXT]
ESA APPRISE Oncology Program Enrollment for Hospitals

Thank you for participating in the ESA APPRISE Oncology Program

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**

<table>
<thead>
<tr>
<th>Site ID</th>
<th>Site Name</th>
<th>Site Address</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
</tr>
</thead>
<tbody>
<tr>
<td>7890</td>
<td>Phoenix Hospital</td>
<td>112 Elm</td>
<td>Phoenix</td>
<td>AZ</td>
<td>85027</td>
</tr>
</tbody>
</table>

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 1-866-204-8099 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.
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

Healthcare Provider and Hospital Designee Materials
Dear Healthcare Provider (HCP): Letter to Newly Identified HCPs who may Prescribe, or Prescribe and Dispense, ESAs for Patients with Cancer
Dear Healthcare Provider (HCP) Letter to Pharmacists/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 Affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer
ESA APPRISSE Oncology Program Training Module for Healthcare Providers
ESA APPRISSE Oncology Program Training Module for Hospital Designees
ESA APPRISSE Oncology Program Enrollment Form for Healthcare Providers
ESA APPRISSE Oncology Program Enrollment Form for Hospitals
ESA APPRISSE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)
Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics
ESA APPRISSE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) - SPANISH

Prescribing Information
Aranesp® (darbepoetin alfa) Prescribing Information
Eprex® (epoetin alfa) Prescribing Information
Procrit® (epoetin alfa) Prescribing Information

Materials for Patients
Acknowledgment Form
ESA APPRISSE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)
ESA APPRISSE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) - SPANISH

Medication Guides
Aranesp® (darbepoetin alfa) Medication Guide
Eprex® (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®)
Eprex® (epoetin alfa) Instructions for Use
Procrit® (epoetin alfa) Instructions for Use

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.
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

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>ZIP Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1234 N MAIN ST</td>
<td>WAYNE</td>
<td>PA</td>
<td>19087</td>
</tr>
</tbody>
</table>

- 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

[Next]
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**

- **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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**Material Order: Address Selection**

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

**Practice Locations**
Please select/enter your shipping address

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<thead>
<tr>
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<th>ZIP Code</th>
</tr>
</thead>
<tbody>
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<td>1234 N MAIN ST</td>
<td>WAYNE</td>
<td>PA</td>
<td>19087</td>
</tr>
</tbody>
</table>

- Primary practice is not listed

**Practice Contact Information**

- **First Name**
- **Last Name**
- **Email Address**
- **Phone (###-###-####)**
- **Fax (###-###-####)**

- Select the registered primary contact

**Next**
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**

- **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

Next
Material Order: Specify Type and Quantity

Materials Selection

Select the materials you would like to order

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Medication Guides</strong></td>
</tr>
<tr>
<td>0</td>
<td>Aranesp® (darbepoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>0</td>
<td>Aranesp® (darbepoetin alfa) Medication Guide - SPANISH</td>
</tr>
<tr>
<td>0</td>
<td>Epogen® (epoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>0</td>
<td>Epogen® (epoetin alfa) Medication Guide - SPANISH</td>
</tr>
<tr>
<td>0</td>
<td>Procrit® (epoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>0</td>
<td>Procrit® (epoetin alfa) Medication Guide - SPANISH</td>
</tr>
<tr>
<td></td>
<td><strong>Tear Pads</strong></td>
</tr>
<tr>
<td>0</td>
<td>Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms</td>
</tr>
<tr>
<td>0</td>
<td>Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms - SPANISH</td>
</tr>
</tbody>
</table>
# Material Order: Your Current Order Items

## Current Order

The items that you have selected are listed below.

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Order Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Aranesp® (darbepoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>10</td>
<td>Epogen® (epoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>15</td>
<td>Procrit® (epoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>25</td>
<td>Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms</td>
</tr>
</tbody>
</table>

**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.*
Material Order: Your Current Order Items

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

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Order Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Aranesp® (darbepoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>10</td>
<td>Epogen® (epoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>15</td>
<td>Procrit® (epoetin alfa) Medication Guide</td>
</tr>
<tr>
<td>25</td>
<td>Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms</td>
</tr>
</tbody>
</table>

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.
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:

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:

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
- Aranesp® (darbepoetin alfa) Medication Guide
- Aranesp® (darbepoetin alfa) Medication Guide - SPANISH
- Epogen® (epoetin alfa) Medication Guide
- 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 (Simplicity®)
- Epogen® (epoetin alfa) Instructions for Use
- Procrit® (epoetin alfa) Instructions for Use

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.
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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>ZIP Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dalgleish Health System</td>
<td>123 Main St</td>
<td>Los Angeles</td>
<td>CA</td>
<td>90001</td>
</tr>
<tr>
<td>Imperial Penn Medical Center</td>
<td>456 Race St</td>
<td>Los Angeles</td>
<td>CA</td>
<td>90001</td>
</tr>
<tr>
<td>Dana-Farber Cancer Institute</td>
<td>123 Main St</td>
<td>Los Angeles</td>
<td>CA</td>
<td>90001</td>
</tr>
<tr>
<td>MD Anderson Cancer Hospital</td>
<td>456 Race St</td>
<td>Los Angeles</td>
<td>CA</td>
<td>90001</td>
</tr>
</tbody>
</table>

ESAs APPRISE Oncology Program Enrollment Form for Hospitals
ESAs APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)
Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics
ESAs APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) - SPANISH

Prescribing Information
- Aranesp® (darbepoetin alfa) Prescribing Information
- Epoetin® (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
- Aranesp® (darbepoetin alfa) Medication Guide
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- Epoetin® (epoetin alfa) Medication Guide
- Epoetin® (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 Syringes (Simplisca®)
- Epoetin® (epoetin alfa) Instructions for Use
- Procrit® (epoetin alfa) Instructions for Use

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free here.
ESA APPRISE Oncology Program Login

Username

Password

Login

First time user? Forgot password? Click here.
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

Continue

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

Continue
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.
## Practice Location Management

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>ZIP Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dakota Health System</td>
<td>123 Main St</td>
<td>Los Angeles</td>
<td>CA</td>
<td>90001</td>
</tr>
<tr>
<td>Imperial Point Medical Center</td>
<td>456 Race St</td>
<td>Los Angeles</td>
<td>CA</td>
<td>90001</td>
</tr>
<tr>
<td>Sibley Memorial Hospital</td>
<td>123 Main St</td>
<td>Los Angeles</td>
<td>CA</td>
<td>90001</td>
</tr>
<tr>
<td>AMI Culver Union Hospital</td>
<td>456 Race St</td>
<td>Los Angeles</td>
<td>CA</td>
<td>90001</td>
</tr>
</tbody>
</table>

[Add Practice Location] [Remove Practice Location]
Add Practice Location

Practice Location Lookup

<table>
<thead>
<tr>
<th>ZIP</th>
<th>City</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

[Search]

Practice Location Search Results

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>ZIP Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Practice location not listed

Practice Contact Information

First Name
Last Name
Address
City
State
ZIP Code
Email Address
Confirm Email Address
Phone (###-###-####)
Fax (###-###-####)

[Add Practice Location] [Cancel]
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
City
State
ZIP Code
Email Address
Confirm Email Address
Phone (###-###-####)
Fax (###-###-####)

Add Practice Location

Cancel
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
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
Change Password

New Password

Confirm New Password

Cancel  Change Password
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.
# Hospital HCP Enrollment Management Report

## Affiliate Dashboard

<table>
<thead>
<tr>
<th>Enrollment ID</th>
<th>First Name</th>
<th>Last Name</th>
<th>Designation</th>
<th>Completed Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>548789</td>
<td>John</td>
<td>Smith</td>
<td>MD</td>
<td>01/24/2010</td>
</tr>
<tr>
<td>563482</td>
<td>Jane</td>
<td>Wintersmith</td>
<td>MD</td>
<td>03/03/2010</td>
</tr>
<tr>
<td>457687</td>
<td>Allison</td>
<td>Tennant</td>
<td>MD</td>
<td>03/30/2010</td>
</tr>
</tbody>
</table>

[Add Provider] [Remove Provider]
Affiliated Provider Management

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

**Enrollment ID**

[Add Provider] [Remove Provider]
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
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.

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

Update Profile

Cancel
Change Password

New Password

Confirm New Password

Cancel  Change Password
Hospital HCP Management Report

Hospital Information

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

Hospital HCP Management Report

<table>
<thead>
<tr>
<th>Enrollment ID</th>
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<td>Tennant</td>
<td>MD</td>
<td>03/30/2010</td>
</tr>
</tbody>
</table>
Frequently Asked Questions (FAQs)

Questions

Who is a ESA?

Who must enrol in the ESA APPRIZE Assessment Providers and cancer Patients with Risk Information for the Safe use of ESA Apprize Oncology Program?

At enrollment, patients are placed into one of four categories based on whether they have a history of cancer and whether they have been exposed to certain medications. Patients can be either "risk-free" or "high risk." The categories are:

1. **Risk-Free Patients:**
   - No history of cancer
   - No exposure to certain medications

2. **High Risk Patients:**
   - Have a history of cancer
   - Expose to certain medications

3. **Low Risk Patients:**
   - No history of cancer
   - Expose to certain medications

4. **Very Low Risk Patients:**
   - Have a history of cancer
   - No exposure to certain medications

What are the benefits of enrolling in the ESA APPIRIZE Oncology Program?

The ESA APPIRIZE Oncology Program provides a number of benefits for eligible patients, including:

1. **Risk Stratification:**
   - Identifying patients at risk of anemia
   - Tailoring treatment to reduce anemia

2. **Evidence-Based Care:**
   - Providing evidence-based care for anemia
   - Reducing unnecessary blood transfusions

3. **Patient Safety:**
   - Ensuring patient safety during chemotherapy
   - Reducing the risk of adverse events

What are the consequences of not enrolling in the ESA APPIRIZE Oncology Program?

Patients who do not enroll in the ESA APPIRIZE Oncology Program may be at risk for:

1. **Increased Anemia Risk:**
   - Anemia may be more severe
   - Treatment may be less effective

2. **Increased Adverse Events:**
   - More frequent blood transfusions
   - Increased risk of infection

3. **Increased Costs:**
   - Higher costs for medications and therapies
   - Additional costs for medical care

How do I enroll in the ESA APPIRIZE Oncology Program?

Patients can enroll in the ESA APPIRIZE Oncology Program by speaking with their healthcare provider. Providers can request enrollment for eligible patients by using the ESA APPIRIZE Oncology Program website or contacting the program directly.

Can patients receive ESA treatments without enrolling in the ESA APPIRIZE Oncology Program?

Yes, patients can receive ESA treatments without enrolling in the ESA APPIRIZE Oncology Program. However, patients who enroll in the program may receive additional benefits, such as risk stratification and evidence-based care.

What are the eligibility criteria for the ESA APPIRIZE Oncology Program?

Patients are eligible for the ESA APPIRIZE Oncology Program if they:

1. **Have a Cancer Diagnosis:**
   - Diagnosis within the past 10 years

2. **Have had chemotherapy:**
   - Within the last 12 months

3. **Are not enrolled in another ESA program:**
   - This includes any other ESA programs available to patients

4. **Are not currently receiving ESA treatment:**
   - Patients who are receiving ESA treatment cannot enroll

5. **Are not enrolled in another ESA program:**
   - This includes any other ESA programs available to patients

What is the enrollment process for the ESA APPIRIZE Oncology Program?

The enrollment process for the ESA APPIRIZE Oncology Program typically involves:

1. **Patient Referral:**
   - Healthcare providers can refer eligible patients to the program

2. **Phone Assessment:**
   - Eligible patients will undergo a phone assessment to determine eligibility

3. **Enrollment:**
   - Eligible patients will be enrolled in the program

4. **Ongoing Support:**
   - Patients will receive ongoing support and monitoring from the program

What is the role of the ESA APPIRIZE Oncology Program in managing patient care?

The ESA APPIRIZE Oncology Program plays a critical role in managing patient care by:

1. **Identifying Anemia Risk:**
   - Identifying patients at risk of anemia

2. **Tailoring Treatment:**
   - Tailoring treatment to reduce anemia

3. **Evidence-Based Care:**
   - Providing evidence-based care for anemia

4. **Patient Safety:**
   - Ensuring patient safety during chemotherapy

5. **Reducing Costs:**
   - Reducing unnecessary blood transfusions

What is the impact of the ESA APPIRIZE Oncology Program on patient outcomes?

The ESA APPIRIZE Oncology Program has been shown to improve patient outcomes by:

1. **Reducing Anemia:**
   - Reducing the incidence of anemia

2. **Improving Quality of Life:**
   - Improving patients' quality of life

3. **Reducing Adverse Events:**
   - Reducing the risk of adverse events

4. **Reducing Costs:**
   - Reducing unnecessary medical costs

What are the limitations of the ESA APPIRIZE Oncology Program?

While the ESA APPIRIZE Oncology Program provides many benefits, there are some limitations to the program, including:

1. **Eligibility Criteria:**
   - Eligibility criteria may limit the number of patients who can enroll

2. **Enrollment Process:**
   - The enrollment process may be time-consuming

3. **Resource Availability:**
   - Resource availability may limit the number of patients who can be enrolled

4. **Patient Compliance:**
   - Patient compliance with the program may be an issue

What is the future of the ESA APPIRIZE Oncology Program?

The future of the ESA APPIRIZE Oncology Program is uncertain at this time. The program may continue to evolve and improve as more research is conducted and as new evidence becomes available.

References


Contact Us

If you have any questions or concerns about the ESA APPIRIZE Oncology Program, please contact us at 1-800-555-5555.

Visit us online at ESAAPPIRIZE.com

Information is correct as of the date of publication. For the most current information, please visit the ESA APPIRIZE Oncology Program website.

References


Contact Us

If you have any questions or concerns about the ESA APPIRIZE Oncology Program, please contact us at 1-800-555-5555.

Visit us online at ESAAPPIRIZE.com

Information is correct as of the date of publication. For the most current information, please visit the ESA APPIRIZE Oncology Program website.
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.
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.
<table>
<thead>
<tr>
<th>When I prescribe or order an ESA therapy for a patient with cancer in a hospital:</th>
<th>• 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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 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.</td>
<td></td>
</tr>
<tr>
<td>• 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.</td>
<td></td>
</tr>
<tr>
<td>• I will ensure the ESA that I prescribe will be dispensed under my supervision.</td>
<td></td>
</tr>
</tbody>
</table>

| 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 | State | ____________________________ |
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, or contact your local Amgen or Janssen Products, LP Field Representative.
Training Module for Healthcare Providers

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

Reference ID: 3429800
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.
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).

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

*Q1 = 25th percentile  Q3 = 75th percentile

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®.
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).
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.
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.
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.
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.
SECTION 3
PROGRAM REQUIREMENTS AND MATERIALS FOR HEALTHCARE PROVIDERS
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.

*Note: 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.*
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 in the Forms & Resources section.
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.
SECTION 4
HEALTHCARE PROVIDER ENROLLMENT
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.
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®.
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). 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)]
*Or modified version consistent with allowable changes
Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.
Aranesp® and Epogen® are registered trademarks of Amgen Inc. Procrit® is a registered trademark of Janssen Products, LP.
This document has been required by the US Food and Drug Administration as part of a Risk Evaluation and Mitigation Strategy (REMS) for Aranesp®, Epogen® and Procrit®.
**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

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

---

**Written Permission to Share Information**

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.

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* _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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**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.
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 ________________________________
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, or contact your local Amgen or Janssen Products, LP Field Representative.
ESA APPRISE
ONCOLOGY PROGRAM

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

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.
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 available at www.esa-apprise.com.
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).

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

*Q1 = 25th percentile  Q3 = 75th percentile

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®.
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).

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®.
**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 ≥ 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).
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.

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®.
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.
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.
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.

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

The correct statement is: ESAs should be discontinued following the completion of a chemotherapy course.
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 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.
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.
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 in the Forms & Resources section.

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.
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.
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 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.
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.
Aranesp® and Epogen® are registered trademarks of Amgen Inc. Procrit® is a registered trademark of Janssen Products, L.P.
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®.
Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer

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. 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.

*ESA = erythropoiesis stimulating agent [Aranesp® (darbepoetin alfa)/Epogen® (epoetin alfa)/Procrit® (epoetin alfa)]. Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules. Aranesp® and Epogen® are registered trademarks of Amgen Inc. Procrit® is a registered trademark of Janssen Products, LP. This document has been required by the US Food and Drug Administration as part of a Risk Evaluation and Mitigation Strategy (REMS) for Aranesp®, Epogen®, and Procrit®.
Mitigation Strategy (REMS) for Aranesp®

This document has been required by the US Food and Drug Administration as part of a Risk Evaluation and Mitigation Strategy (REMS) for Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa) to address risks associated with 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.

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

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.

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

- I understood 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 other federal and nonfederal health agencies and organizations.
  - I can cancel my permission at any time by providing written notice to my healthcare provider.
  - My permission lasts until the Program ends

Written Permission to Share Information

Signature of patient or patient representative

Printed name of patient representative

Date (MM/DD/YY)

Healthcare Provider Acknowledgment

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

- I understood 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 other federal and nonfederal health agencies and organizations.
  - 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 Healthcare Provider

Printed name of Healthcare Provider

Date (MM/DD/YY)

Patient Acknowledgment of ESA Benefits and Risks

Benefits: People with anemia have a lower-than-normal number of red blood cells (RBCs). ESAs help the human body produce RBCs to help your body make more oxygen and energy for the cells. 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

I am willing to sign this form.

Signature

Date (MM/DD/YY)

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

/s/

ANN T FARRELL
12/31/2013