Initial REMS Approval: 02/2010

Most Recent Modification: 12/2013

BL 103951 ARANESP® (DARBEPOETIN ALFA)

Amgen Inc.
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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

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

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

II. REMS ELEMENTS

A. Elements to Assure Safe Use

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

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

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

      i. Review the prescribing information.

[1] For the purposes of this REMS, the terms prescribe and prescription include medication orders in the clinic or hospital settings.

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

ii. Complete the ESA APPRISE Oncology Program Training Module for Healthcare Providers.

iii. Complete and sign the ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers and submit it to the ESA APPRISE Oncology Program Call Center.

iv. Agree to counsel each patient on the risks of ESAs by reviewing and signing the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) (or modified version consistent with the allowable changes) and to provide a copy of the signed Acknowledgment Form to the patient.

1) HCPs in a private clinic practice setting agree to maintain a completed Acknowledgment Form for auditing purposes in a manner that does not require the disclosure of the patient's medical record, and to store the Acknowledgment Forms on-site and/or archive them in a retrievable manner.

2) HCPs in a hospital setting agree to provide the completed Acknowledgment Forms to the Hospital Designee responsible for maintaining and storing the forms on-site and/or archiving them in a retrievable manner.

b. Amgen will:

i. Send a DHCP Letter to non-certified HCPs who may prescribe, or prescribe and dispense, Aranesp for patients with cancer instructing them how to become certified in the ESA APPRISE Oncology Program.

ii. Provide each certified HCP a unique ESA APPRISE Oncology Program enrollment identification (ID) number, which will be used to confirm certification in the Program.

iii. Maintain a secure and accurate database of HCPs certified in the ESA APPRISE Oncology Program.

iv. Ensure that, as part of the enrollment process, HCPs receive the following materials that are part of the ESA APPRISE Oncology Program:

1) Dear Healthcare Provider (DHCP) Letter to Newly Identified HCPs who may Prescribe, or Prescribe and Dispense, ESAs for Patients with Cancer

2) ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers

3) ESA APPRISE Oncology Program Training Module for Healthcare Providers

4) Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer

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

6) Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics

v. Inform certified HCPs following important modifications to the Aranesp REMS or to the ESA APPRISE Oncology Program

vi. Ensure that ESA APPRISE Oncology Program materials are available on the Program website or can be obtained by contacting the ESA APPRISE Oncology Program Call Center at 1-866-284-8089.

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

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

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

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

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

i. Complete the ESA APPRISE Oncology Program Training Module for Hospital Designees.

ii. Agree to assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in hospital(s) for which they are responsible.

iii. Agree to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the ESA APPRISE Oncology Program, such that:

1) Aranesp is only dispensed to patients with cancer after verifying:

a) that the healthcare provider who prescribed Aranesp for patients with cancer is certified in the ESA APPRISE Oncology Program; and

b) the discussion between the patient and ESA APPRISE Oncology Program-certified provider on the risks of Aranesp therapy is documented by patient and provider signatures on the Acknowledgment Form (or modified version consistent with the allowable changes) prior to initiation of each new course of Aranesp therapy.

2) If an HCP that prescribes Aranesp is not certified in the ESA APPRISE Oncology Program, the provider will be notified that they are not able to prescribe Aranesp for patients with cancer.

iv. Oversee compliance with program auditing to assess the effectiveness of the ESA APPRISE Oncology Program.

v. Maintain evidence of compliance with the ESA APPRISE Oncology Program for auditing purposes, as follows:

1) documentation (ie, unique enrollment ID number) that each HCP in the hospital who prescribes Aranesp for patients with cancer is certified in the ESA APPRISE Oncology Program

2) documentation of the risk:benefit discussion between certified provider and patient on the Acknowledgment Form (or modified version consistent with the allowable changes) for each patient with cancer for whom an Aranesp prescription was filled; the Acknowledgment Forms are to be stored on-site and/or archived in a retrievable manner.

vi. Complete and sign the ESA APPRISE Oncology Program Enrollment Form for Hospitals and submit it to the ESA APPRISE Oncology Program Call Center.

b. Amgen will:

i. Send a Dear Director of Pharmacy/Administrator Letter to non-certified hospitals that dispense Aranesp for patients with cancer, instructing them how to become certified in the ESA APPRISE Oncology Program.

ii. Provide each hospital with a unique ESA APPRISE Oncology Program enrollment ID number that will be used to confirm certification in the Program.

iii. Ensure that the ESA APPRISE Oncology Program Call Center maintains a secure and accurate database of certified hospitals in the ESA APPRISE Oncology Program.

iv. Ensure that, as part of the enrollment process, the Hospital Designee receives the following materials that are part of the ESA APPRISE Oncology Program:

1) Dear Healthcare Provider (DHCP) Letter to Directors of Pharmacy/Administrators of Newly Identified Hospitals That Dispense ESAs to Patients With Cancer
2) ESA APPRISE Oncology Program Enrollment Form for Hospitals
3) ESA APPRISE Oncology Program Training Module for Hospital Designees
4) Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer
5) Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer
6) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form
7) Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics

v. Inform certified Hospital Designees following important modifications to the Aranesp REMS or to the ESA APPRISE Oncology Program.

vi. Ensure that ESA APPRISE Oncology Program materials are available on the Program website or can be obtained by contacting the ESA APPRISE Oncology Program Call Center at 1-866-284-8089.

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

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

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

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

B. Implementation System

The Implementation System includes the following:

1. Amgen will monitor compliance with completion of the Acknowledgment Form (or modified version consistent with the allowable changes) and will work to improve implementation if non-compliance is identified.

    a. Amgen will allow certain changes to the Acknowledgment Form to ensure that the form can be adapted by hospitals and private practices to be compatible with their existing systems. The allowable formatting-related changes are:

        i. Removal of title instruction and footnoted text

        ii. Addition of patient identifier and/or clinic/hospital identifiers (eg, name and/or logo, barcodes)

        iii. Changes to make the form compatible with existing systems, including electronic- and paper-based systems

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

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

    b. The ESA APPRISE Oncology Program will audit selected private practice-based clinics. For each audit, a sample of at least 100 clinics that have purchased ESAs during the audit period that were not included in the prior audit will be selected. Each audit will be conducted according to a time schedule that allows these data to be provided with each REMS assessment. HCPs in private practice-based clinics will be audited by the ESA APPRISE Oncology Program to demonstrate evidence of compliance with the Program as follows:

        i. That the number of HCPs who prescribe ESAs for patients with cancer in the private practice-based clinic is not greater than the number of HCPs in the private practice-based setting that are certified in the ESA APPRISE Oncology Program (by unique ESA APPRISE Oncology Program enrollment ID number).

        ii. That the number of patient- and HCP-signed Acknowledgment Forms retained at the clinic is not less than the number of patients with cancer initiating a new course of ESA therapy.

    c. For hospitals, the ESA APPRISE Oncology Program will identify at least 25 hospitals with ESA use in patients with cancer during the audit period. The audits will be conducted according to a time schedule that allows these data to be provided with each REMS assessment. These hospitals will be audited by the ESA APPRISE Oncology Program to demonstrate evidence of compliance with the Program as follows:

i. That the documentation maintained by hospitals demonstrates that each HCP in the hospitals who prescribe ESAs for patients with cancer is certified in the ESA APPRISE Oncology Program (by unique ESA APPRISE Oncology Program enrollment ID number).

ii. That the number of patient- and HCP-signed Acknowledgment Forms retained at the hospital is not less than the number of patients with cancer initiating a new course of ESA therapy. For the audits to be effective, hospitals will implement a means to determine the total number of individual patients that received Aranesp based on orders and prescriptions written.

2. For sites that are non-compliant, Amgen will request that the non-compliant clinic or hospital develop, submit, and implement a plan to correct findings. The site will automatically be included in a for-cause audit for the subsequent audit cycle. If continued non-compliance is identified, the HCP or hospital will have their access to ESAs suspended. Removal from the Suspended Access List will require correction of non-compliance with the REMS requirements.

3. Amgen will instruct distributors not to ship an ESA to a hospital or HCP at a private practice-based clinic without confirmation from the ESA APPRISE Oncology Program Call Center that the hospital or the HCP is certified or that certification is not applicable (ie, the hospital does not dispense an ESA for patients with cancer or the HCP does not prescribe, or prescribe and dispense, an ESA for patients with cancer in a private practice-based clinic).

4. Amgen will monitor HCP and hospital certification on an ongoing basis to evaluate compliance with the ESA APPRISE Oncology Program certification requirements and will work to improve implementation of this element.

5. If there are important modifications to the Aranesp REMS and to the ESA APPRISE Oncology Program, Amgen will update all affected materials and notify certified HCPs and hospitals, as applicable.

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

C. Timetable for Submission of Assessments of the REMS

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

janssen

AMGEN Oncology

Name
Address
City, State Zip

[Date]

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

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

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

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®.

ESA APPRISE ONCOLOGY PROGRAM

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

Reference ID: 3429792

Name
Address
City, State Zip

[Date]

Re: ACTION REQUIRED for Hospitals That Dispense ESAs (erythropoiesis stimulating agents) for Patients With Cancer

Dear Hospital Administrator/Director of Pharmacy,

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

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Sincerely,

Amgen
Janssen Products, LP

Enclosures:
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Procrit® is a registered trademark of Janssen Products, LP.

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

ESA APPRISE Oncology Program Web Site

Site Screenshots

September 5, 2013

Version 4.0.10

FDA Updates

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Recent Program Modifications ✖

Key Highlights

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

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

Train and enroll
Learn more
Access forms & resources
Recent Program Modifications

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Eryth n® (epoetin alfa), and
Procr sk Evaluation and
Mitiga atment for a patient
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Amge viders and cancer
Patie a REMS designed for
HCPs

Wha gram?

- In rrence in patients wi
  - ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

Key Program Requirements

Healthcare Providers	Hospitals
1. Complete Training	**1a. Select a Hospital Designee** **1b. Hospital Designee Completes Training**
2. Enroll in the ESA APPRISE Oncology Program	**2. Enroll in the ESA APPRISE Oncology Program**
3. Counsel and Document • Counsel each patient on the risks of ESAs prior to each new course of ESA therapy. • Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form and providing each patient a copy of the signed form.	**3. Implement** • Hospital Designee to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program.

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.

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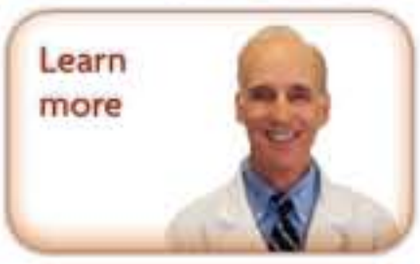
AMGEN Oncology

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 (**A**ssisting **P**roviders and cancer **P**atients with **R**isk **I**nformation for the **S**afe use of **E**SAs) Oncology Program as part of a REMS designed for HCPs treating patients with an ESA for their cancer.

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

- **Increased risk of death and/or increased risk of tumor progression or recurrence in patients with cancer.**
  - ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

Key Program Requirements

Healthcare Providers	Hospitals
1. Complete Training	**1a. Select a Hospital Designee** **1b. Hospital Designee Completes Training**
2. Enroll in the ESA APPRISE Oncology Program	**2. Enroll in the ESA APPRISE Oncology Program**
3. Counsel and Document • Counsel each patient on the risks of ESAs prior to each new course of ESA therapy. • Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form and providing each patient a copy of the signed form.	**3. Implement** • Hospital Designee to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program.

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.

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This program is intended for residents of the United States only.
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AMGEN Oncology

Recent Program Modifications

- **The goal of the REMS has been changed to focus on the risks of using ESAs for patients with cancer:**
  The goal of the REMS is to support informed discussions between patients with cancer and their healthcare providers by:
  - educating healthcare providers about the risks and safe use conditions of Aranesp® (darbepoetin alfa) and Epogen®/Procrit® (epoetin alfa) for patients with cancer.
  - informing patients about the risks of shortened overall survival and/or increased risk of tumor progression or recurrence when Aranesp® 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:**
  - Do not fax or mail a copy of the Acknowledgment Form to the ESA APPRISE Oncology Program Call Center.
  - Completed Acknowledgment Forms (or modified version consistent with the allowable changes) must be available to the ESA APPRISE Oncology Program for auditing purposes in a manner that does not require disclosure of the patient's medical record.
  - In a private practice-based clinic, store the forms on-site and/or archive them through an electronic medical records system as long as they are retrievable.
  - The hospital process has not changed. In a hospital, provide the completed Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms.

- **A copy of the signed Acknowledgment Form must be provided to each patient. Please note that this is a new requirement.**

- **The Acknowledgment Form has been revised:**
  - ESA benefit information has been added in the section for patients. The risk language has been updated to focus on using ESA therapy for patients with cancer.

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.

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AMGEN Oncology

ESA APPRISE Oncology Program Overview

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

1. What is the goal of the Program?

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

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

2. What are the key Program requirements?

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

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

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

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

Training and Enrollment

*or modified version consistent with the allowable changes

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AMGEN Oncology

Reference ID: 3429792

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

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EMS designed for
HCPs treating patients with an ESA for their cancer.

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

- **Increased risk of death and/or increased risk of tumor progression or recurrence in patients with cancer.**
  - ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

Key Program Requirements

Healthcare Providers	Hospitals
1. Complete Training	**1a. Select a Hospital Designee** **1b. Hospital Designee Completes Training**
2. Enroll in the ESA APPRISE Oncology Program	**2. Enroll in the ESA APPRISE Oncology Program**
3. Counsel and Document • Counsel each patient on the risks of ESAs prior to each new course of ESA therapy. • Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form and providing each patient a copy of the signed form.	**3. Implement** • Hospital Designee to establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that the hospital is in compliance with the Program.

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?

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- Call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089, or
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*Additional information on REMS may be found at www.FDA.gov

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

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AMGEN Oncology

Welcome to the ESA APPRISE Oncology Program

Recent Program Modifications

Begin Training & Enrollment ×

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

○ Yes ◉ No

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

Non-prescribing HCPs-Training only (click here)

Close

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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

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Key Program Requirements

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AMGEN Oncology

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 (**A**ssisting **P**roviders and cancer **P**atients with **R**isk **I**nformation for the **S**afe use of **E**SAs) 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.

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Click the next button to continue

Training & Enrollment Progress

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AMGEN Oncology

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

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

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

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

*Q1= 25th percentile
Q3= 75th percentile

Decreased Overall Survival

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

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

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

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

Decreased Progression-free Survival and Overall Survival

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

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

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

Decreased Locoregional Control

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

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

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

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

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

Yes, I have reviewed all of Section 1

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AMGEN Oncology

Reference ID: 3429792

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.

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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

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AMGEN Oncology

Section 2: Appropriate Use of ESAs for Patients With Cancer

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  - in patients with cancer
  - as a substitute for RB
- ESAs have not been sho

Important Dosing and Tre

- Initiate ESAs in patients
- Use the lowest dose of E
- Discontinue ESAs followi

Please see the Aranesp®, E Medication Guides.

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

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Healthcare Provider Knowledge Check

Correct.

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

Next

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

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

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Healthcare Provider Knowledge Check ✖

Incorrect.

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

Next

Important Dosing and Tre
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Healthcare Provider Knowledge Check ✖

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

True | False

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Next

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

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

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

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AMGEN Oncology

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 RB
- ESAs have not been sho

Healthcare Provider Knowledge Check ✖

Correct.

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

Next

Important Dosing and Tre
- Initiate ESAs in patients
- Use the lowest dose of E
- Discontinue ESAs followi

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  - in patients with cancer
  - as a substitute for RB
  - ESAs have not been sho

Healthcare Provider Knowledge Check

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

True | False

Important Dosing and Tre

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- Use the lowest dose of E
- Discontinue ESAs followi

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Healthcare Provider Knowledge Check ✖

Correct.

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

Continue to Section 3

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

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

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

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Section 2: Appropriate Use of ESAs for Patients With Cancer

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Healthcare Provider Knowledge Check

Incorrect.

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

Continue to Section 3

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

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

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Section 3: Program Requirements and Materials for Healthcare Providers

HCP requirements for patient counseling

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

- Counsel each patient on the risks (increased risk of mortality and increased risk of tumor progression or recurrence) of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy by reviewing the Acknowledgment Form.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with each patient has occurred by completing the Acknowledgment Form with each patient and providing each patient a copy of the signed form.

CLICK HERE

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

CLICK HERE

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

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

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

These materials include:

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

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

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

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

Yes, I have reviewed all of Section 3

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Section 4: Healthcare Provider Enrollment

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

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

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

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

Yes, I have reviewed all of Section 4

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ESA APPRISE Oncology Program Enrollment for Healthcare Providers

I agree to the following:

I have reviewed the appropriate current prescribing information and Medication Guide for Aranesp® or Epogen®/Procrit®.

- I understand that ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
- I understand that in order to decrease these risks, the lowest dose of ESAs should be used to avoid red blood cell (RBC) transfusions.
- I understand that ESAs are indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
- I understand that ESAs are not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.
- I understand that ESAs are not indicated for use in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- I understand that ESAs are not indicated for use in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- I understand that ESAs have not been shown to improve quality of life, fatigue, or patient well-being.
- I understand that ESAs should be discontinued following the completion of a chemotherapy course.

I have reviewed the ESA APPRISE Oncology Program requirements and agree that:

- I will discuss my patient's questions or concerns about Aranesp® or Epogen®/Procrit®.
- I will counsel each patient on the risks (increased risk of mortality and increased risk of tumor progression or recurrence) of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy by reviewing the Acknowledgment Form.
- I will document that the discussion with each patient has occurred by completing an Acknowledgment Form with each patient and providing each patient a copy of the signed form.
  - By signing the patient section of the form, the patient acknowledges the following:
    - I acknowledge that my healthcare provider did the following before I received my first dose of Aranesp® or Epogen®/Procrit®:
      - Told me about the benefits and risks of ESA therapy.
      - Answered all of my questions or concerns about my treatment with an ESA.
  - By signing the HCP section of the form, as a healthcare provider certified in the ESA APPRISE Oncology Program, I acknowledge that prior to the initiation of each new course of ESA therapy:
    - I counseled the patient on the risks of Aranesp® or Epogen®/Procrit® by reviewing the Acknowledgment Form.
    - I discussed all concerns and answered all questions the patient had about treatment with Aranesp® or Epogen®/Procrit® to the best of my ability.
    - The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

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 patient's medical record; and to store the Acknowledgment Forms on-site and/or archive them in a retrievable manner. • 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. • I will ensure the ESA that I prescribe will be dispensed under my supervision.
When I prescribe or order an ESA for a patient with cancer in a hospital:	• I will provide the completed 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.

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

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

Yes, I agree to all the above

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ESA APPRISE Oncology Program Enrollment for Healthcare Providers

* indicates a required field.

Prescriber Information

My primary practice location is (select one) *
- Private practice-based clinic
- Hospital or outpatient facility affiliated with a hospital/institution

First Name *

Last Name *

Professional Designation *

Title

Email Address *

Confirm Email Address *

NPI # *

- or -

State/Territory License # and Issuing State *

Electronic Signature

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

Signature * First and Last Name

Date * Today's date (mm/dd/yyyy)

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ESA APPRISE Oncology Program Enrollment for Healthcare Providers

* indicates a required field.

Primary Practice Location

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

ZIP - or - City State Search

Please select your Primary Practice Location

Primary Practice Search Results

Practice Name	Address	City	State	ZIP Code

☐ Primary practice is not listed

Primary Practice Contact Information

☐ Same as Contact Information and Primary Location Address

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

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ESA APPRISE Oncology Program Enrollment for Healthcare Providers

* indicates a required field.

Primary Practice Location

Primary Practice Name *

Address *

City *

State *

ZIP Code *

☐ Search by ZIP code or City/State

Primary Practice Contact Information

☐ Same as Contact Information and Primary Location Address

First Name *

Last Name *

Address *

City *

State *

ZIP Code *

Email Address *

Confirm Email Address *

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

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

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ESA APPRISE Oncology Program Enrollment for Healthcare Providers

* indicates a required field.

Primary Practice Address Match

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

New Practice Name
1001 Main Blvd
Los Angeles, CA 90001

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

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

Your entered address:

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

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ESA APPRISE Oncology Program Enrollment for Healthcare Providers

* indicates a required field.

Additional Practice Locations

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

ZIP | City | State
- or -
ZIP | City | State
- or -
ZIP | City | State
- or -

Search

Please select up to 10 Secondary Practice Locations

Secondary Practice Search Results

	Practice Name	Address	City	State	ZIP Code

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ESA APPRISE Oncology Program Enrollment for Healthcare Providers

Thank you for participating in the ESA APPRISE Oncology Program

Print this Page

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

Enrollment ID: ***123456***
Your Enrollment ID will be required on every ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form.

Site Affiliation(s)

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

You will receive the materials for the ESA APPRISE Oncology Program. The materials will be shipped to each private practice location in the above list. If your primary practice location is a hospital, these materials will be sent to the Hospital Designee.

These materials include:

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

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

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

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

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

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Training Module for Hospital Designees

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

The ESA APPRISE (**A**ssisting **P**roviders and cancer **P**atients with **R**isk **I**nformation for the **S**afe use of **E**SAs) Oncology Program is part of the REMS. This Training Module is required for certification in the ESA APPRISE Oncology Program and is intended for Hospital Designees at hospitals that dispense ESAs for patients with cancer.

The goal of the REMS for Aranesp® and Epogen®/Procrit® is:
To support informed discussions between patients with cancer and their healthcare providers by:

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

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

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

This Training Module features four sections:

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

Section 2: Appropriate use of ESAs for patients with cancer

Section 3: HCP and Hospital Designee Program requirements and materials

Section 4: Enrollment

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

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

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

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

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

*Q1= 25th percentile
Q3= 75th percentile

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.

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

Yes, I have reviewed all of Section 1

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AMGEN Oncology

Reference ID: 3429792

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

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AMGEN Oncology

Section 2: Appropriate Use of ESAs for Patients With Cancer

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  - in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - in patients with cancer
  - as a substitute for RB
- ESAs have not been sho

Important Dosing and Tre

- Initiate ESAs in patients
- Use the lowest dose of E
- Discontinue ESAs followi

Please see the Aranesp®, E Medication Guides.

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

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

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

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

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  - in patients with cancer
  - as a substitute for RB
- ESAs have not been sho

Hospital Designee Knowledge Check ✖

Correct.

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

Next

Important Dosing and Tre
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- Use the lowest dose of E
- Discontinue ESAs followi

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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
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Important Dosing and Tre

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- Discontinue ESAs followi

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Hospital Designee Knowledge Check

Incorrect.

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

Next

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Yes, I have reviewed all of Section 2
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Important Dosing and Tre

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- Use the lowest dose of E
- Discontinue ESAs followi

Please see the Aranesp®, E Medication Guides.

Hospital Designee Knowledge Check ✖

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

True | False

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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
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- Discontinue ESAs followi

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Hospital Designee Knowledge Check ✖

Incorrect.

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

Next

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

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

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  - in patients with cancer
  - as a substitute for RB
- ESAs have not been sho

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

Important Dosing and Tre
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Yes, I have reviewed all of Section 2
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Important Dosing and Tre

- Initiate ESAs in patients
- Use the lowest dose of E
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Please see the Aranesp®, E Medication Guides.

Hospital Designee Knowledge Check

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

True | False

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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
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Hospital Designee Knowledge Check

Correct.

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

Continue to Section 3

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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
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Hospital Designee Knowledge Check

Incorrect.

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

Continue to Section 3

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

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

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

HCP requirements for patient counseling

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

- Counsel each patient on the risks (increased risk of mortality and increased risk of tumor progression or recurrence) of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy by reviewing the Acknowledgment Form.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with each patient has occurred by completing each section of the Acknowledgment Form with each patient and providing each patient a copy of the signed form.

CLICK HERE

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

Hospital Designee Requirements

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

CLICK HERE

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

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

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

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

- ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms
- Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics
- Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer
- Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer

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

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

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

Yes, I have reviewed all of Section 3

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Reference ID: 3429792

Section 4: Hospital Designee Enrollment

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

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

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

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

Yes, I have reviewed all of Section 4

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ESA APPRISE Oncology Program Enrollment for Hospitals

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

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

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

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

Yes, I agree to all the above

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ESA APPRISE Oncology Program Enrollment for Hospitals

* indicates a required field.

Authorized Hospital Designee Information

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 * First and Last Name

Date * Today's date (mm/dd/yyyy)

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ESA APPRISE Oncology Program Enrollment for Hospitals

* indicates a required field.

Hospital Enrollment Information

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

ZIP - or - City State Search

Please select your hospital

Hospital Main Address Search Results

Practice Name	Address	City	State	ZIP Code

☐ Hospital main address is not listed

Hospital Contact Information for Receipt of Program Materials

☐ Click here if different from the authorized designee

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AMGEN Oncology

ESA APPRISE Oncology Program Enrollment for Hospitals

* indicates a required field.

Hospital Enrollment Information

Hospital Name *

Address *

City *

State *

ZIP Code *

HIN # *

- or -

DDD # *

☐ Search by ZIP code or City/State

Hospital Contact Information for Receipt of Program Materials

☐ Click here if different from the authorized designee

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ESA APPRISE Oncology Program Enrollment for Hospitals

* indicates a required field.

Hospital Enrollment Information

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

ZIP - or - City State Search

Please select your hospital

Hospital Main Address Search Results

Practice Name	Address	City	State	ZIP Code

☐ Hospital main address is not listed

Hospital Contact Information for Receipt of Program Materials

First Name *

Last Name *

☐ Same as hospital main address

Address *

City *

State *

ZIP Code *

Email Address *

Confirm Email Address *

Password *

Confirm Password *

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

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

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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.

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AMGEN Oncology

ESA APPRISE Oncology Program Enrollment for Hospitals

* indicates a required field.

Hospital Enrollment Information

Hospital Name *

Address *

City *

State *

ZIP Code *

HIN # *

- or -

DDD # *

☐ Search by ZIP code or City/State

Hospital Contact Information for Receipt of Program Materials

First Name *

Last Name *

☐ Same as hospital main address

Address *

City *

State *

ZIP Code *

Email Address *

Confirm Email Address *

Password *

Confirm Password *

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

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

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ESA APPRISE Oncology Program Enrollment for Hospitals

* indicates a required field.

Hospital Enrollment Information Address Match

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

New Hospital Name
1001 Main Blvd
Los Angeles, CA 90001

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

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

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

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

Your entered address:

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

Training & Enrollment Progress

BACK NEXT

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ESA APPRISE Oncology Program Enrollment for Hospitals

Thank you for participating in the ESA APPRISE Oncology Program

Print this Page

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

Enrollment ID: ***123456***
This enrollment ID number allows you to identify HCPs enrolled at your location.

Enrolled Hospital

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

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

Materials provided include:

- ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms
- Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics
- Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer
- Steps for Hospitals and Hospital/Institution-affiliated Outpatient Facilities That Dispense ESAs to Patients With Cancer

Until your materials arrive, download and print the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form.

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

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

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

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

Prescribing Information

- Aranesp® (darbepoetin alfa) Prescribing Information
- Epogen® (epoetin alfa) Prescribing Information
- Procrit® (epoetin alfa) Prescribing Information

Materials for Patients

Acknowledgment Form

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

Medication Guides

- 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 (SingleJect®)
- Epogen® (epoetin alfa) Instructions for Use
- Procrit® (epoetin alfa) Instructions for Use

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Reference ID: 3429792

Material Order: Address Selection

Personal Information

The Enrollment ID is associated to the following individual.

First Name John
Last Name Smith
Email Address john.smith@email.com

Practice Locations

Please select/enter your shipping address

Practice Locations

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

☐ Primary practice is not listed

Practice Contact Information

Confirm the following contact information is correct

First Name Allison
Last Name Tennant
Email Address allison.tennant@email.com
Phone (###-###-####) 215-555-1212
Fax (###-###-####) 215-555-1213

☐ Primary contact is not listed

Next

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Material Order: Address Selection

* indicates a required field.

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

Next

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Material Order: Address Selection

indicates a required field.

Personal Information

The Enrollment ID is associated to the following individual.

First Name John
Last Name Smith
Email Address john.smith@email.com

Practice Locations

Please select/enter your shipping address

Practice Locations

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

☐ Primary practice is not listed

Practice Contact Information

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

☐ Select the registered primary contact

Next

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Material Order: Address Selection

indicates a required field.

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

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Material Order: Specify Type and Quantity

Materials Selection

Select the materials you would like to order

Quantity	Item
Medication Guides	
0	Aranesp® (darbepoetin alfa) Medication Guide
0	Aranesp® (darbepoetin alfa) Medication Guide - SPANISH
0	Epogen® (epoetin alfa) Medication Guide
0	Epogen® (epoetin alfa) Medication Guide - SPANISH
0	Procrit® (epoetin alfa) Medication Guide
0	Procrit® (epoetin alfa) Medication Guide - SPANISH
Tear Pads	
0	Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms
0	Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Forms - SPANISH

Next

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Material Order: Your Current Order Items

Current Order

The items that you have selected are listed below.

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

Delivered to the following location

Practice Name
1234 N MAIN ST
WAYNE, PA 19087

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

Submit Order

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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

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

Delivered to
Practice Name
1234 N MAIN ST
WAYNE, PA 19087

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

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Forms & Resources

Materials for Healthcare Providers

Order Program Materials

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

Enrollment ID:

Continue

Download Your Customized Acknowledgment Form ×

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

Enrollment ID

Cancel | Next >

Hea

- ESA APPRISE Oncology Program Training Module for Healthcare Providers
- ESA APPRISE Oncology Program Training Module for Hospital Designees
- ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers
- ESA APPRISE Oncology Program Enrollment Form for Hospitals
- ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)
- Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics
- ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) - SPANISH

Prescribing Information

- Aranesp® (darbepoetin alfa) Prescribing Information
- Epogen® (epoetin alfa) Prescribing Information
- Procrit® (epoetin alfa) Prescribing Information

Materials for Patients

Acknowledgment Form

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

Medication Guides

- 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 (SingleJect®)
- Epogen® (epoetin alfa) Instructions for Use
- Procrit® (epoetin alfa) Instructions for Use

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Forms & Resources

Materials for Healthcare Providers

Order Program Materials

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

Enrollment ID:

Continue

Download Your Customized Acknowledgment Form ×

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

Forms Available to Download

Name	Address	City	State	ZIP Code
Dakota Health System	123 Main St	Los Angeles	CA	90001
Imperial Point Medical Center	456 Race St	Los Angeles	CA	90001
Sibley Memorial Hospital	123 Main St	Los Angeles	CA	90001
AMI Culver Union Hospital	456 Race St	Los Angeles	CA	90001

Hea

ESA APPRISE Oncology Program Enrollment Form for Hospitals

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

Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics

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

Prescribing Information

Aranesp® (darbepoetin alfa) Prescribing Information

Epogen® (epoetin alfa) Prescribing Information

Procrit® (epoetin alfa) Prescribing Information

Materials for Patients

Acknowledgment Form

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

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

Medication Guides

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 (SingleJect®)

Epogen® (epoetin alfa) Instructions for Use

Procrit® (epoetin alfa) Instructions for Use

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ESA APPRISE ONCOLOGY PROGRAM

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

Full Prescribing Information including Boxed WARNINGS

Medication Guides

Login

Home | Important Safety Information | Overview | Training & Enrollment | Forms & Resources | FAQs | Contact Us

ESA APPRISE Oncology Program Login

Username

Password

Login

First time user? Forgot password? Click here.

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Full Prescribing Information including Boxed WARNINGS

Medication Guides

Login

Home | Important Safety Information | Overview | Training & Enrollment | Forms & Resources | FAQs | Contact Us

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

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ESA APPRISE Oncology Program Healthcare Provider

Practice Location Management
Add and remove practice locations.

Edit Profile
Review and edit your contact information.

Change Password
Change your password.

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Practice Location Management

Practice Locations

	Practice Name	Address	City	State	ZIP Code
☐	Dakota Health System	123 Main St	Los Angeles	CA	90001
☐	Imperial Point Medical Center	456 Race St	Los Angeles	CA	90001
☐	Sibley Memorial Hospital	123 Main St	Los Angeles	CA	90001
☐	AMI Culver Union Hospital	456 Race St	Los Angeles	CA	90001

Add Practice Location | Remove Practice Location

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Add Practice Location

Practice Location Lookup

ZIP - or - City State Search

Practice Location Search Results

Practice Name	Address	City	State	ZIP Code

☐ Practice location not listed

Practice Contact Information

First Name

Last Name

☐ Address same as Practice Location information above

Address

City

State

ZIP Code

Email Address

Confirm Email Address

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

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

Cancel | Add Practice Location

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Add Practice Location

Practice Location Lookup

Practice Name

Address

City

State

ZIP Code

Search by ZIP code or City/State

Practice Contact Information

First Name

Last Name

Address same as Practice Location information above

Address

City

State

ZIP Code

Email Address

Confirm Email Address

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

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

Cancel

Add Practice Location

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ESA APPRISE ONCOLOGY PROGRAM

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

Full Prescribing Information including Boxed WARNINGS

Medication Guides

Home | Important Safety Information | Overview | Training & Enrollment | Forms & Resources | FAQs | Contact Us

ESA APPRISE Oncology Program Healthcare Provider » Practice Location Management

Practice Location

Practice Locations

Practice Nam	ZIP Code
Dakota Health System	90001
Imperial Point Medical C	90001
Sibley Memorial Hospita	90001
AMI Culver Union Hospit	90001

Add Practice Location | R

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

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Edit Profile

Prescriber Information

First Name

Last Name

Professional Designation

Title

Email Address

Confirm Email Address

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

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

NPI #

- or -

State/Territory License # and Issuing State

Cancel

Update Profile

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Change Password

New Password

Confirm New Password

Cancel

Change Password

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ESA APPRISE Oncology Program Hospital Designee

Hospital HCP Enrollment Management Report
Manage your prescribers for this location.

Edit Profile
Keep your profile updated.

Change Password
Change your password.

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Hospital HCP Enrollment Management Report

Affiliate Dashboard

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

Add Provider | Remove Provider

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Hospital HCP Enrollment Management Report

Affiliate Dashboard

Enrollment ID		Date
548789	John	/24/2010
563482	Jane	/03/2010
457687	Allisor	/30/2010

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

Cancel | Add Provider

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ESA APPRISE ONCOLOGY PROGRAM

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

Full Prescribing Information including Boxed WARNINGS

Medication Guides

Home | Important Safety Information | Overview | Training & Enrollment | Forms & Resources | FAQs | Contact Us

ESA APPRISE Oncology Program Hospital Designee » Hospital HCP Enrollment Management Report

Hospital HCP Enr

Affiliate Dashboard

Enrollment ID		Date
548789	John	/24/2010
563482	Jane	/03/2010
457687	Allisor	/30/2010

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

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Edit Profile

Authorized Hospital Designee Information

First Name

Last Name

Title

Email Address

Confirm Email Address

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

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

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

Cancel | Update Profile

Hospital HCP Enrollment Management Report Access

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

Hospital Username **Password** Update

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Change Password

New Password

Confirm New Password

Cancel

Change Password

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Hospital HCP Management Report

Hospital Information

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

Hospital HCP Management Report

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

Print

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AMGEN Oncology

Frequently Asked Questions (FAQs)

Questions

What is a REMS?

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

Is re-enrollment required?

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

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

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

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

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

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

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

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

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

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

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

Answers

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

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

Back to Top

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

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

Back to Top

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

Back to Top

I enrolled in the ESA APPRISE Oncology Program through my office, but now I want to initiate a new course of ESA therapy to a patient in the hospital. Do I have to re-enroll?
No, a single enrollment will apply across all your practice locations.

Back to Top

As a nephrologist treating patients with ESAs for the anemia of Chronic Kidney Disease (CKD) who may also have cancer or are cancer survivors, do I need to enroll in the ESA APPRISE Oncology Program?
No, the ESA APPRISE Oncology Program is required for HCPs prescribing ESAs for the anemia resulting from cancer chemotherapy.

Back to Top

I am a healthcare provider treating a patient who has cancer or is a cancer survivor but is now being treated with an ESA for anemia for non-oncology indications. Should this patient be subject to the ESA APPRISE Oncology Program requirements?
No, these patients are not subject to the ESA APRISE Oncology Program.

Back to Top

What are the consequences of not training and enrolling in the ESA APPRISE Oncology Program?
Failure to comply with Program requirements, including training and enrollment, will result in suspension of access to ESAs.

Back to Top

How long will this enrollment take and can my nurse or office manager enroll for me?
The training and enrollment should take approximately 10-15 minutes to complete and can be completed on this website or facilitated by field-based company representatives. The ESA APPRISE Oncology Program requires that the actual prescribing HCP complete the training and enrollment in the Program.

Back to Top

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

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

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We utilize standard forms for documenting patient consent. Can we modify our existing consent form to be like the Acknowledgment Form you provided?
The Program requires the risk:benefit discussion be documented using the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form).

To learn more about allowable changes to the Acknowledgment Form, please refer to the Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics flashcard which can be found under the Forms & Resources tab.

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Can the discussion with the patient on ESA risks and benefits be conducted by a nurse or other qualified healthcare provider?
This Program specifically requires that healthcare providers who prescribe, or prescribe and dispense, ESAs conduct and document the ESA risk:benefit discussion. However, nurses and other qualified healthcare providers may still be involved in their standard patient education processes.

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Can patients still receive their ESAs if there is no enrolled provider on site on the actual day of injection?
Yes, as long as the patient receiving the ESA had the risk:benefit discussion and signed the Acknowledgment Form with the trained and enrolled provider of the ESA prior to receiving the injection.

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When I treat a patient with cancer, do I need to send the completed Acknowledgment Form to the ESA APPRISE Oncology Program Call Center?
No. In private practice-based clinics, store the Acknowledgment Form(s) on-site and/or archive them through an electronic medical record system as long as they are retrievable. In hospitals, provide the completed Acknowledgment Form to the Hospital Designee responsible for maintaining and storing the forms.

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AMGEN Oncology

Reference ID: 3429792

Contact Us

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

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

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AMGEN Oncology

ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers

janssen

AMGEN Oncology

Aranesp® *(darbepoetin alfa)*, **Epogen®** *(epoetin alfa)*, and **Procrit®** *(epoetin alfa)* are **E**rythropoiesis **S**timulating **A**gents (ESAs) used for patients with cancer

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

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

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

By completing this form, I agree to the following:

- I have reviewed the appropriate current prescribing information for Aranesp® or Epogen®/Procrit®.
  - I understand that ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
  - I understand that in order to decrease these risks, the lowest dose of ESAs should be used to avoid red blood cell (RBC) transfusions.
  - I understand that ESAs are indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
  - I understand that ESAs are not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.
  - I understand that ESAs are not indicated for use in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - I understand that ESAs are not indicated for use in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
  - I understand that ESAs have not been shown to improve quality of life, fatigue, or patient well-being.
  - I understand that ESAs should be discontinued following the completion of a chemotherapy course.
- I have reviewed the ESA APPRISE Oncology Program requirements and agree that:
  - I will discuss my patient's questions or concerns about Aranesp® or Epogen®/Procrit®.
  - I will counsel each patient on the risks (increased risk of mortality and increased risk of tumor progression or recurrence) of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy by reviewing the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form).
  - I will document that the discussion with each patient has occurred by completing an Acknowledgment Form with each patient and providing each patient a copy of the signed form.
- By signing the patient section of the form, the patient acknowledges the following:
  - I acknowledge that my healthcare provider did the following before I received my first dose of Aranesp® or Epogen®/Procrit®:
    - Told me about the benefits and risks of ESA therapy.
    - Answered all of my questions or concerns about my treatment with an ESA.
- By signing the HCP section of the form, as a healthcare provider certified in the ESA APPRISE Oncology Program, I acknowledge that prior to the initiation of each new course of ESA therapy:
  - I counseled the patient on the risks of Aranesp® or Epogen®/Procrit® by reviewing the Acknowledgment Form.
  - I discussed all concerns and answered all questions the patient had about treatment with Aranesp® or Epogen®/Procrit® to the best of my ability.
  - The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

ESA APPRISE ONCOLOGY PROGRAM

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

ESA APPRISE Oncology Program
Enrollment Form for Healthcare Providers

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 patient's medical record, and to store the Acknowledgment Forms on-site and/or archive them in a retrievable manner. • 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. • I will ensure the ESA that I prescribe will be dispensed under my supervision.
When I prescribe or order an ESA therapy for a patient with cancer in a hospital:	• 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.	

Full name (print) _____ Degree _____

Signature _____ Date _____

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

Phone _____ Fax _____ Email _____

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

Practice location name _____

Practice address _____

City _____ State _____ ZIP _____

Practice contact name _____ Phone _____

Fax _____ Email _____

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

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

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.

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®.

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

janssen

Aranesp® (darbepoetin alfa)

EPOGEN® (EPOETIN ALFA) RECOMBINANT

PROCRIT® EPOETIN ALFA

AMGEN Oncology

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

Training Module for Healthcare Providers

Reference ID: 3429792

V5 10/13

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 (**A**ssisting **P**roviders and cancer **P**atients with **R**isk **I**nformation for the **S**afe use of **E**SAs) Oncology Program is part of the REMS. This training module is required for certification in the ESA APPRISE Oncology Program and is intended for healthcare providers (HCPs) who prescribe, or prescribe and dispense, ESAs for patients with cancer.

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

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

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

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

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

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

Reference ID: 3429792

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

Training Module for Healthcare Providers

This Training Module features four sections:

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

Section 2: Appropriate use of ESAs for patients with cancer

Section 3: HCP Program requirements and materials

Section 4: Enrollment

Please see the Aranesp®, Epogen®, and Procrit® prescribing information, including **Boxed WARNINGS** and Medication Guides available at www.esa-apprise.com.

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.
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V5 10/13

Reference ID: 3429792

ESA APPRISE ONCOLOGY PROGRAM

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

SECTION 1
KEY SAFETY INFORMATION FOR USE OF ESAs FOR PATIENTS WITH CANCER

ESA APPRISE ONCOLOGY PROGRAM

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

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

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

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

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

*Q1 = 25th percentile Q3 = 75th percentile

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Reference ID: 3429792

ESA APPRISE ONCOLOGY PROGRAM

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

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

Decreased Overall Survival

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

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

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

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

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

Decreased Progression-free Survival and Overall Survival

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

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

Study 5 was a randomized, placebo-controlled study in 351 head and neck cancer patients where epoetin beta or placebo was administered to achieve target hemoglobins ≥ 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).

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Reference ID: 3429792

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

Decreased Locoregional Control

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

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

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Reference ID: 3429792

SECTION 2
APPROPRIATE USE OF ESAs FOR PATIENTS WITH CANCER

ESA APPRISE ONCOLOGY PROGRAM

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

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.

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

Section 2
Healthcare Provider Knowledge Check

Answer true or false to the following statements:

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

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

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

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

Section 2
Answers to the Healthcare Provider Knowledge Check

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

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

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

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Reference ID: 3429792

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

SECTION 3
PROGRAM REQUIREMENTS AND MATERIALS FOR HEALTHCARE PROVIDERS

ESA APPRISE ONCOLOGY PROGRAM

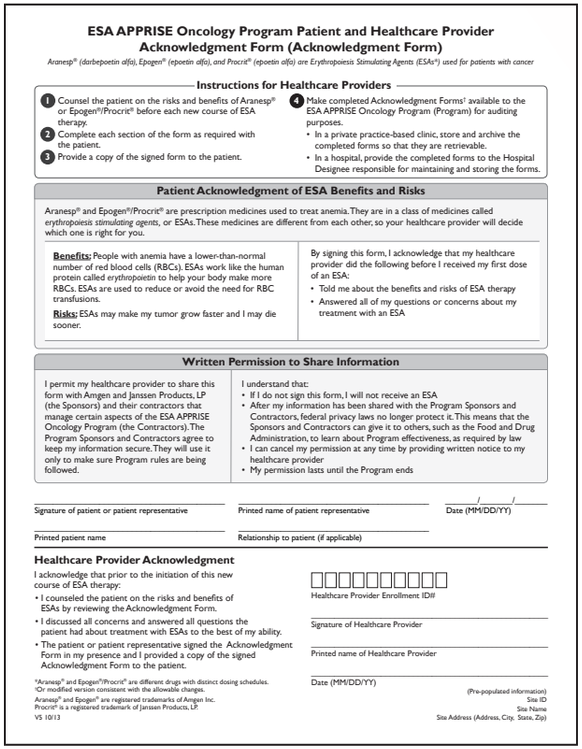
Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs

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.



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

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

Instructions for Healthcare Providers

1. Counsel the patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient.
4. Make completed Acknowledgment Forms† available to the ESA APPRISE Oncology Program (Program) for auditing purposes.
   - In a private practice-based clinic, store and archive the completed forms so that they are retrievable.
   - In a hospital, provide the completed forms to the Hospital Designee responsible for maintaining and storing the forms.

Patient Acknowledgment of ESA Benefits and Risks

Aranesp® and Epogen®/Procrit® are prescription medicines used to treat anemia. They are in a class of medicines called *erythropoiesis stimulating agents*, or ESAs. These medicines are different from each other, so your healthcare provider will decide which one is right for you.

Benefits: People with anemia have a lower-than-normal number of red blood cells (RBCs). ESAs work like the human protein called *erythropoietin* to help your body make more RBCs. ESAs are used to reduce or avoid the need for RBC transfusions.

Risks: ESAs may make my tumor grow faster and I may die sooner.

By signing this form, I acknowledge that my healthcare provider did the following before I received my first dose of an ESA:

- Told me about the benefits and risks of ESA therapy
- Answered all of my questions or concerns about my treatment with an ESA

Written Permission to Share Information

I permit my healthcare provider to share this form with Amgen and Janssen Products, LP (the Sponsors) and their contractors that manage certain aspects of the ESA APPRISE Oncology Program (the Contractors). The Program Sponsors and Contractors agree to keep my information secure. They will use it only to make sure Program rules are being followed.

I understand that:

- If I do not sign this form, I will not receive an ESA
- After my information has been shared with the Program Sponsors and Contractors, federal privacy laws no longer protect it. This means that the Sponsors and Contractors can give it to others, such as the Food and Drug Administration, to learn about Program effectiveness, as required by law
- I can cancel my permission at any time by providing written notice to my healthcare provider
- My permission lasts until the Program ends

Signature of patient or patient representative | Printed name of patient representative | Date (MM/DD/YY) ___/___/___

Printed patient name | Relationship to patient (if applicable)

Healthcare Provider Acknowledgment

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

- I counseled the patient on the risks and benefits of ESAs by reviewing the Acknowledgment Form.
- I discussed all concerns and answered all questions the patient had about treatment with ESAs to the best of my ability.
- The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

Healthcare Provider Enrollment ID#

Signature of Healthcare Provider

Printed name of Healthcare Provider

Date (MM/DD/YY)

(Pre-populated information)
Site ID
Site Name
Site Address (Address, City, State, Zip)

*Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.
†Or modified version consistent with the allowable changes.
Aranesp® and Epogen® are registered trademarks of Amgen Inc.
Procrit® is a registered trademark of Janssen Products, LP.
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Aranesp® 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®.

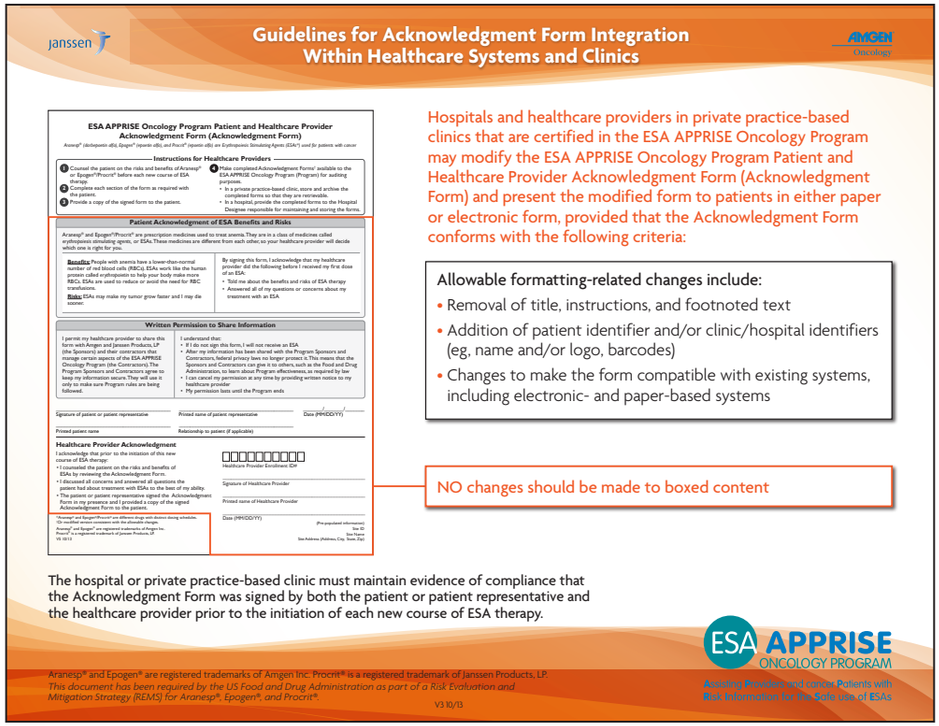
Reference ID: 3429792

ESA APPRISE ONCOLOGY PROGRAM

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

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.



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Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics

AMGEN Oncology

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

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

Instructions for Healthcare Providers

1. Counsel the patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient.
4. Make completed Acknowledgment Forms[1] available to the ESA APPRISE Oncology Program (Program) for auditing purposes.
   - If a private practice-based clinic, store and archive the completed forms so that they are retrievable.
   - In a hospital, provide the completed forms to the Hospital Designee responsible for maintaining and storing the forms.

Patient Acknowledgment of ESA Benefits and Risks

Aranesp® and Epogen®/Procrit® are prescription medicines used to treat anemia. They are in a class of medicines called erythropoiesis stimulating agents, or ESAs. These medicines are different from each other, so your healthcare provider will decide which one is right for you.

Benefits: People with anemia have a lower-than-normal number of red blood cells (RBCs). ESAs work like the human protein called erythropoietin to help your body make more RBCs. ESAs are used to reduce or avoid the need for RBC transfusions.

Risks: ESAs may make my tumor grow faster and I may die sooner.

By signing this form, I acknowledge that my healthcare provider did the following before I received my first dose of an ESA:

- Told me about the benefits and risks of ESA therapy
- Answered all of my questions or concerns about my treatment with an ESA

Written Permission to Share Information

I permit my healthcare provider to share this form with Amgen and Janssen Products, LP (the Sponsors) and their contractors that manage certain aspects of the ESA APPRISE Oncology Program (the Contractors). The Program Sponsors and Contractors agree to keep my information secure. They will use it only to make sure Program rules are being followed.

I understand that:

- If I do not sign this form, I will not receive an ESA
- After my information has been shared with the Program Sponsors and Contractors, federal privacy laws no longer protect it. This means that the Sponsors and Contractors can give it to others, such as the Food and Drug Administration, to learn about Program effectiveness, as required by law
- I can cancel my permission at any time by providing written notice to my healthcare provider
- My permission lasts until the Program ends

Signature of patient or patient representative | Printed name of patient representative | Date (MM/DD/YY)

Printed patient name | Relationship to patient (if applicable)

Healthcare Provider Acknowledgment

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

- I counseled the patient on the risks and benefits of ESAs by reviewing the Acknowledgment Form.
- I discussed all concerns and answered all questions the patient had about treatment with ESAs to the best of my ability.
- The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

Healthcare Provider Enrollment ID#

Signature of Healthcare Provider

Printed name of Healthcare Provider

Date (MM/DD/YY)

(Pre-populated information)
Site ID
Site Name
Site Address (Address, City, State, Zip)

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[1]On modified version consistent with the allowable changes.
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Procrit® is a registered trademark of Janssen Products, LP.
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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.

ESA APPRISE ONCOLOGY PROGRAM

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

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®.

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ESA APPRISE ONCOLOGY PROGRAM

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

Reference ID: 3429792

Section 3
Program Requirements and Materials for Healthcare Providers

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

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

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

These materials include:

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

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

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Reference ID: 3429792

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

SECTION 4
HEALTHCARE PROVIDER ENROLLMENT

ESA APPRISE ONCOLOGY PROGRAM

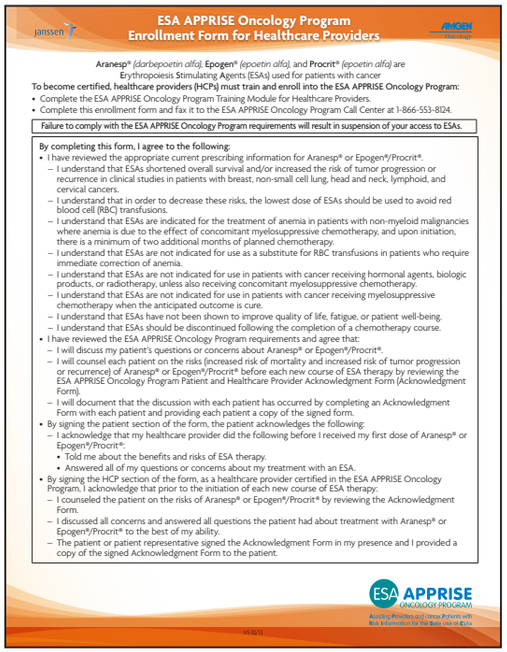
Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs

HCP 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



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ESA APPRISE Oncology Program
Enrollment Form for Healthcare Providers

AMGEN

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

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

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

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

By completing this form, I agree to the following:

- I have reviewed the appropriate current prescribing information for Aranesp® or Epogen®/Procrit®.
  - I understand that ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
  - I understand that in order to decrease these risks, the lowest dose of ESAs should be used to avoid red blood cell (RBC) transfusions.
  - I understand that ESAs are indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
  - I understand that ESAs are not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.
  - I understand that ESAs are not indicated for use in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - I understand that ESAs are not indicated for use in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
  - I understand that ESAs have not been shown to improve quality of life, fatigue, or patient well-being.
  - I understand that ESAs should be discontinued following the completion of a chemotherapy course.
- I have reviewed the ESA APPRISE Oncology Program requirements and agree that:
  - I will discuss my patient's questions or concerns about Aranesp® or Epogen®/Procrit®.
  - I will counsel each patient on the risks (increased risk of mortality and increased risk of tumor progression or recurrence) of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy by reviewing the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form).
  - I will document that the discussion with each patient has occurred by completing an Acknowledgment Form with each patient and providing each patient a copy of the signed form.
- By signing the patient section of the form, the patient acknowledges the following:
  - I acknowledge that my healthcare provider did the following before I received my first dose of Aranesp® or Epogen®/Procrit®:
    - Told me about the benefits and risks of ESA therapy.
    - Answered all of my questions or concerns about my treatment with an ESA.
- By signing the HCP section of the form, as a healthcare provider certified in the ESA APPRISE Oncology Program, I acknowledge that prior to the initiation of each new course of ESA therapy:
  - I counseled the patient on the risks of Aranesp® or Epogen®/Procrit® by reviewing the Acknowledgment Form.
  - I discussed all concerns and answered all questions the patient had about treatment with Aranesp® or Epogen®/Procrit® to the best of my ability.
  - The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

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

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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.
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Reference ID: 3429792

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

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ESA APPRISE
ONCOLOGY PROGRAM

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

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Steps for Healthcare Providers Who Prescribe, or Prescribe and Dispense, ESAs for Patients With Cancer

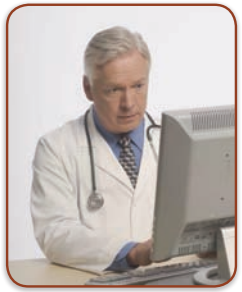
AMGEN Oncology

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.

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.

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.

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)].
†Or modified version consistent with allowable changes.
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Reference ID: 3429792

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

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

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

Instructions for Healthcare Providers

1. Counsel the patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient.
4. Make completed Acknowledgment Forms† available to the ESA APPRISE Oncology Program (Program) for auditing purposes.
   - In a private practice-based clinic, store and archive the completed forms so that they are retrievable.
   - In a hospital, provide the completed forms to the Hospital Designee responsible for maintaining and storing the forms.

Patient Acknowledgment of ESA Benefits and Risks

Aranesp® and Epogen®/Procrit® are prescription medicines used to treat anemia. They are in a class of medicines called *erythropoiesis stimulating agents,* or ESAs. These medicines are different from each other, so your healthcare provider will decide which one is right for you.

Benefits: People with anemia have a lower-than-normal number of red blood cells (RBCs). ESAs work like the human protein called *erythropoietin* to help your body make more RBCs. ESAs are used to reduce or avoid the need for RBC transfusions.

Risks: ESAs may make my tumor grow faster and I may die sooner.

By signing this form, I acknowledge that my healthcare provider did the following before I received my first dose of an ESA:

- Told me about the benefits and risks of ESA therapy
- Answered all of my questions or concerns about my treatment with an ESA

Written Permission to Share Information

I permit my healthcare provider to share this form with Amgen and Janssen Products, LP (the Sponsors) and their contractors that manage certain aspects of the ESA APPRISE Oncology Program (the Contractors). The Program Sponsors and Contractors agree to keep my information secure. They will use it only to make sure Program rules are being followed.

I understand that:

- If I do not sign this form, I will not receive an ESA
- After my information has been shared with the Program Sponsors and Contractors, federal privacy laws no longer protect it. This means that the Sponsors and Contractors can give it to others, such as the Food and Drug Administration, to learn about Program effectiveness, as required by law
- I can cancel my permission at any time by providing written notice to my healthcare provider
- My permission lasts until the Program ends

Signature of patient or patient representative _____

Printed name of patient representative _____

Date (MM/DD/YY) _____/_____/_____

Printed patient name _____

Relationship to patient (if applicable) _____

Healthcare Provider Acknowledgment

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

- I counseled the patient on the risks and benefits of ESAs by reviewing the Acknowledgment Form.
- I discussed all concerns and answered all questions the patient had about treatment with ESAs to the best of my ability.
- The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

☐☐☐☐☐☐☐☐☐☐

Healthcare Provider Enrollment ID#

Signature of Healthcare Provider _____

Printed name of Healthcare Provider _____

Date (MM/DD/YY) _____

(Pre-populated information)
Site ID
Site Name
Site Address (Address, City, State, Zip)

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†Or modified version consistent with the allowable changes.

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ESA APPRISE Oncology Program Enrollment Form for Hospitals

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Aranesp® *(darbepoetin alfa)*, **Epogen®** *(epoetin alfa)*, and **Procrit®** *(epoetin alfa)* are **E**rythropoiesis **S**timulating **A**gents (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 _____

ESA APPRISE ONCOLOGY PROGRAM

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

Reference ID: 3429792

ESA APPRISE Oncology Program Enrollment Form for Hospitals

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.

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

Reference ID: 3429792

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Aranesp® (darbepoetin alfa)

EPOGEN® (EPOETIN ALFA) RECOMBINANT

PROCRIT® EPOETIN ALFA

AMGEN Oncology

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

Training Module for Hospital Designees

Reference ID: 3429792

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Training Module for Hospital Designees

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

The ESA APPRISE (**A**ssisting **P**roviders and cancer **P**atients with **R**isk **I**nformation for the **S**afe use of **E**SAs) 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.

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

Training Module for Hospital Designees

This Training Module features four sections:

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

Section 2: Appropriate use of ESAs for patients with cancer

Section 3: HCP and Hospital Designee Program requirements and materials

Section 4: Enrollment

Please see the Aranesp®, Epogen®, and Procrit® prescribing information, including **Boxed WARNINGS** and Medication Guides available at www.esa-apprise.com.

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Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.
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Reference ID: 3429792

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ESA APPRISE ONCOLOGY PROGRAM

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

SECTION 1
KEY SAFETY INFORMATION FOR USE OF ESAs FOR PATIENTS WITH CANCER

ESA APPRISE ONCOLOGY PROGRAM

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

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

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

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

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

*Q1 = 25th percentile Q3 = 75th percentile

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

Decreased Overall Survival

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

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

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

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

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

Decreased Progression-free Survival and Overall Survival

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

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

Study 5 was a randomized, placebo-controlled study in 351 head and neck cancer patients where epoetin beta or placebo was administered to achieve target hemoglobins ≥ 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).

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

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

Decreased Locoregional Control

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

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

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ESA APPRISE ONCOLOGY PROGRAM

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

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.

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ESA APPRISE ONCOLOGY PROGRAM

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

Section 2
Hospital Designee Knowledge Check

Answer true or false to the following statements:

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

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

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

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ESA APPRISE ONCOLOGY PROGRAM

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

Section 2
Answers to the Hospital Designee Knowledge Check

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

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

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

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

SECTION 3
PROGRAM REQUIREMENTS AND MATERIALS FOR HEALTHCARE PROVIDERS AND HOSPITAL DESIGNEES

ESA APPRISE ONCOLOGY PROGRAM

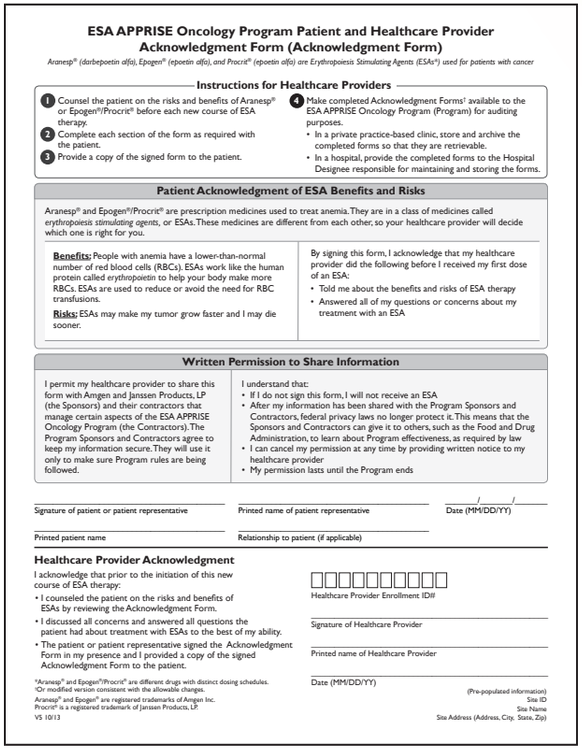
Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs

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.



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

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

Instructions for Healthcare Providers

1. Counsel the patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient.
4. Make completed Acknowledgment Forms† available to the ESA APPRISE Oncology Program (Program) for auditing purposes.
   - In a private practice-based clinic, store and archive the completed forms so that they are retrievable.
   - In a hospital, provide the completed forms to the Hospital Designee responsible for maintaining and storing the forms.

Patient Acknowledgment of ESA Benefits and Risks

Aranesp® and Epogen®/Procrit® are prescription medicines used to treat anemia. They are in a class of medicines called *erythropoiesis stimulating agents*, or ESAs. These medicines are different from each other, so your healthcare provider will decide which one is right for you.

Benefits: People with anemia have a lower-than-normal number of red blood cells (RBCs). ESAs work like the human protein called *erythropoietin* to help your body make more RBCs. ESAs are used to reduce or avoid the need for RBC transfusions.

Risks: ESAs may make my tumor grow faster and I may die sooner.

By signing this form, I acknowledge that my healthcare provider did the following before I received my first dose of an ESA:

- Told me about the benefits and risks of ESA therapy
- Answered all of my questions or concerns about my treatment with an ESA

Written Permission to Share Information

I permit my healthcare provider to share this form with Amgen and Janssen Products, LP (the Sponsors) and their contractors that manage certain aspects of the ESA APPRISE Oncology Program (the Contractors). The Program Sponsors and Contractors agree to keep my information secure. They will use it only to make sure Program rules are being followed.

I understand that:

- If I do not sign this form, I will not receive an ESA
- After my information has been shared with the Program Sponsors and Contractors, federal privacy laws no longer protect it. This means that the Sponsors and Contractors can give it to others, such as the Food and Drug Administration, to learn about Program effectiveness, as required by law
- I can cancel my permission at any time by providing written notice to my healthcare provider
- My permission lasts until the Program ends

Signature of patient or patient representative ____ Printed name of patient representative ____ Date (MM/DD/YY) ___/___/___

Printed patient name ____ Relationship to patient (if applicable) ____

Healthcare Provider Acknowledgment

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

- I counseled the patient on the risks and benefits of ESAs by reviewing the Acknowledgment Form.
- I discussed all concerns and answered all questions the patient had about treatment with ESAs to the best of my ability.
- The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

☐☐☐☐☐☐☐☐☐☐☐
Healthcare Provider Enrollment ID#

Signature of Healthcare Provider ____

Printed name of Healthcare Provider ____

Date (MM/DD/YY) ____

(Pre-populated information)
Site ID
Site Name
Site Address (Address, City, State, Zip)

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ESA APPRISE ONCOLOGY PROGRAM

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

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

Hospital Designee Requirements

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

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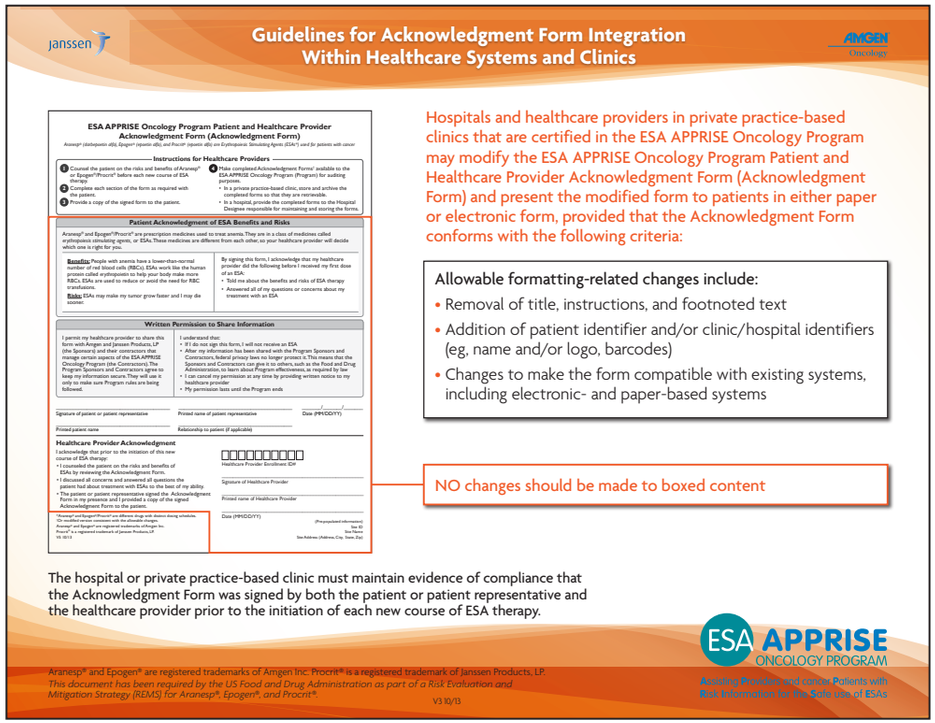
Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs

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.



Janssen

Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics

AMGEN Oncology

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

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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[1] available to the ESA APPRISE Oncology Program (Program) for auditing purposes.
   - In a private practice-based clinic, store and archive the completed forms so that they are retrievable.
   - In a hospital, provide the completed forms to the Hospital Designee responsible for maintaining and storing the forms.

Patient Acknowledgment of ESA Benefits and Risks

Aranesp® and Epogen®/Procrit® are prescription medicines used to treat anemia. They are in a class of medicines called erythropoiesis stimulating agents, or ESAs. These medicines are different from each other, so your healthcare provider will decide which one is right for you.

Benefits: People with anemia have a lower-than-normal number of red blood cells (RBCs). ESAs work like the human protein called erythropoietin to help your body make more RBCs. ESAs are used to reduce or avoid the need for RBC transfusions.

Risks: ESAs may make my tumor grow faster and I may die sooner.

By signing this form, I acknowledge that my healthcare provider did the following before I received my first dose of an ESA:
- Told me about the benefits and risks of ESA therapy
- Answered all of my questions or concerns about my treatment with an ESA

Written Permission to Share Information

I permit my healthcare provider to share this form with Amgen and Janssen Products, LP (the Sponsors) and their contractors that manage certain aspects of the ESA APPRISE Oncology Program (the Contractors). The Program Sponsors and Contractors agree to keep my information secure. They will use it only to make sure Program rules are being followed.

I understand that:
- If I do not sign this form, I will not receive an ESA
- After my information has been shared with the Program Sponsors and Contractors, federal privacy laws no longer protect it. This means that the Sponsors and Contractors can give it to others, such as the Food and Drug Administration, to learn about Program effectiveness, as required by law
- I can cancel my permission at any time by providing written notice to my healthcare provider
- My permission lasts until the Program ends

Signature of patient or patient representative | Printed name of patient representative | Date (MM/DD/YY) ___/___/___

Printed patient name | Relationship to patient (if applicable)

Healthcare Provider Acknowledgment

I acknowledge that prior to the initiation of this new course of ESA therapy:
- I counseled the patient on the risks and benefits of ESAs by reviewing the Acknowledgment Form.
- I discussed all concerns and answered all questions the patient had about treatment with ESAs to the best of my ability.
- The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

□□□□□□□□□□ Healthcare Provider Enrollment ID#

Signature of Healthcare Provider

Printed name of Healthcare Provider

Date (MM/DD/YY)

(Pre-populated information) Site ID | Site Name | Site Address (Address, City, State, Zip)

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Hospitals and healthcare providers in private practice-based clinics that are certified in the ESA APPRISE Oncology Program may modify the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) and present the modified form to patients in either paper or electronic form, provided that the Acknowledgment Form conforms with the following criteria:

Allowable formatting-related changes include:
- Removal of title, instructions, and footnoted text
- Addition of patient identifier and/or clinic/hospital identifiers (eg, name and/or logo, barcodes)
- Changes to make the form compatible with existing systems, including electronic- and paper-based systems

NO changes should be made to boxed content

The hospital or private practice-based clinic must maintain evidence of compliance that the Acknowledgment Form was signed by both the patient or patient representative and the healthcare provider prior to the initiation of each new course of ESA therapy.

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

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

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

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ESA APPRISE ONCOLOGY PROGRAM

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

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.

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®.

Reference ID: 3429792

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

SECTION 4
HOSPITAL DESIGNEE ENROLLMENT

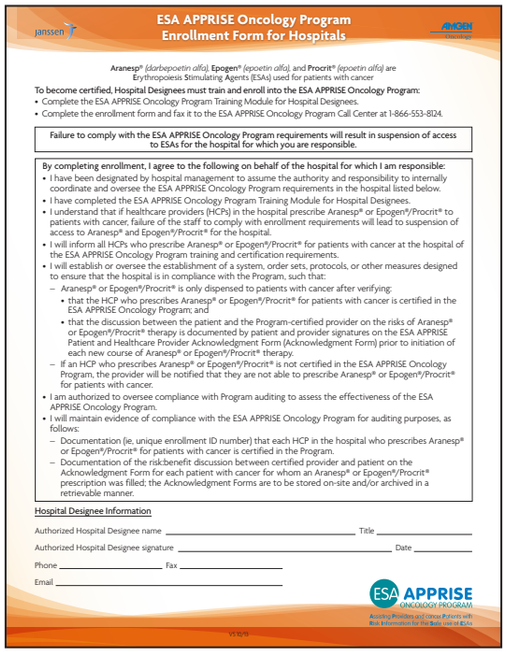
ESA APPRISE ONCOLOGY PROGRAM

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

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



Janssen

ESA APPRISE Oncology Program
Enrollment Form for Hospitals

AMGEN Oncology

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 _____

ESA APPRISE ONCOLOGY PROGRAM

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

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

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ESA APPRISE ONCOLOGY PROGRAM

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

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.

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.

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.

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)].
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ESA APPRISE ONCOLOGY PROGRAM

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

Guidelines for Acknowledgment Form Integration Within Healthcare Systems and Clinics

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AMGEN Oncology

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

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

Instructions for Healthcare Providers

1. Counsel the patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient.
4. Make completed Acknowledgment Forms† available to the ESA APPRISE Oncology Program (Program) for auditing purposes.
   - In a private practice-based clinic, store and archive the completed forms so that they are retrievable.
   - In a hospital, provide the completed forms to the Hospital Designee responsible for maintaining and storing the forms.

Patient Acknowledgment of ESA Benefits and Risks

Aranesp® and Epogen®/Procrit® are prescription medicines used to treat anemia. They are in a class of medicines called *erythropoiesis stimulating agents*, or ESAs. These medicines are different from each other, so your healthcare provider will decide which one is right for you.

Benefits: People with anemia have a lower-than-normal number of red blood cells (RBCs). ESAs work like the human protein called *erythropoietin* to help your body make more RBCs. ESAs are used to reduce or avoid the need for RBC transfusions.

Risks: ESAs may make my tumor grow faster and I may die sooner.

By signing this form, I acknowledge that my healthcare provider did the following before I received my first dose of an ESA:

- Told me about the benefits and risks of ESA therapy
- Answered all of my questions or concerns about my treatment with an ESA

Written Permission to Share Information

I permit my healthcare provider to share this form with Amgen and Janssen Products, LP (the Sponsors) and their contractors that manage certain aspects of the ESA APPRISE Oncology Program (the Contractors). The Program Sponsors and Contractors agree to keep my information secure. They will use it only to make sure Program rules are being followed.

I understand that:

- If I do not sign this form, I will not receive an ESA
- After my information has been shared with the Program Sponsors and Contractors, federal privacy laws no longer protect it. This means that the Sponsors and Contractors can give it to others, such as the Food and Drug Administration, to learn about Program effectiveness, as required by law
- I can cancel my permission at any time by providing written notice to my healthcare provider
- My permission lasts until the Program ends

Signature of patient or patient representative _____ Printed name of patient representative _____ Date (MM/DD/YY) ____/____/____

Printed patient name _____ Relationship to patient (if applicable) _____

Healthcare Provider Acknowledgment

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

- I counseled the patient on the risks and benefits of ESAs by reviewing the Acknowledgment Form.
- I discussed all concerns and answered all questions the patient had about treatment with ESAs to the best of my ability.
- The patient or patient representative signed the Acknowledgment Form in my presence and I provided a copy of the signed Acknowledgment Form to the patient.

☐☐☐☐☐☐☐☐☐☐☐☐ Healthcare Provider Enrollment ID#

Signature of Healthcare Provider _____

Printed name of Healthcare Provider _____

Date (MM/DD/YY) _____

(Pre-populated information)
Site ID
Site Name
Site Address (Address, City, State, Zip)

*Aranesp® and Epogen®/Procrit® are different drugs with distinct dosing schedules.
†Or modified version consistent with the allowable changes.
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Procrit® is a registered trademark of Janssen Products, LP.
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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.

ESA APPRISE ONCOLOGY PROGRAM

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

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

/s/

ANN T FARRELL
12/31/2013