BL 103234 EPOGEN®/ PROCRIT® (EPOETIN ALFA)

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

A. To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Epogen/Procrit by educating them on the risks of Epogen/Procrit.

B. For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs {erythropoiesis stimulating agents}) Oncology Program, is to mitigate the risk of shortened overall survival and/or increased risk of tumor progression or recurrence.

II. REMS ELEMENTS

A. Medication Guides will be provided in accordance with 21 CFR Part 208

In addition to the specific requirements in the elements to assure safe use (sections C.1.b.iv and C.2.b.iv) that apply to HCPs who prescribe Epogen/Procrit, Medication Guides will be provided in accordance with 21 CFR Part 208.

B. Communication Plan

Amgen will maintain a communication plan to HCPs to support implementation of this REMS.

Healthcare Professional Communication: Amgen will send a Dear Healthcare Provider Letter or Dear Director of Pharmacy/Administrator Letter (as applicable) to (1) non-

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

enrolled HCPs who prescribe[2], or prescribe and dispense, Epogen/Procrit for patients with cancer, and (2) non-enrolled hospitals that dispense Epogen/Procrit for patients with cancer, instructing them how to receive training and subsequently enroll in the ESA APPRISE Oncology Program.

ESA APPRISE Oncology Program Website: The website will instruct HCPs to direct any questions to their local field-based personnel or to the ESA APPRISE Oncology Program Call Center at 1-866-284-8089. The ESA APPRISE Oncology Program Call Center provides the following services:

- assistance with program training and enrollment
- supports access to program materials

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

- Dear Healthcare Provider (DHCP) Letter to HCPs who prescribe, or prescribe and dispense, ESAs for patients with cancer
- Dear Director of Pharmacy/Administrator Letter to hospitals that dispense ESAs for patients with cancer
- ESA APPRISE Oncology Program website
- ESA REMS Flashcard

C. Elements to Assure Safe Use

1. Healthcare providers who both prescribe and dispense[3] Epogen/Procrit for patients with cancer in private practice settings are specially certified.

a. Amgen will ensure that appropriately licensed HCPs who both prescribe and dispense Epogen/Procrit for patients with cancer in private practice settings are certified.

b. To become specially certified, HCPs must enroll into the ESA APPRISE Oncology Program by doing the following:

i. Review the full prescribing information which includes the Medication Guide.

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.

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

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

iv. As a prescriber, agree to provide and review the Medication Guide with the oncology patient or patient representative at the initiation of each new course of ESA therapy. After initiation of treatment, and for as long as treatment continues, provide an Epogen/Procrit Medication Guide to each oncology patient once a month during regular office visits—or, if regular office visits occur less frequently than once a month, at the next regularly scheduled office visit.

v. Agree to send a completed signed copy of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form (or modified version consistent with the allowable changes) to the ESA APPRISE Oncology Program Call Center and retain a copy for his/her records.

c. Amgen will:

i. Provide each enrolled HCP a unique ESA APPRISE Oncology Program enrollment number, which will be used to confirm enrollment in the Program.

ii. Ensure that HCPs retrain and re-enroll into the ESA APPRISE Oncology Program every 3 years, and re-enrollment will be evaluated by a comprehensive auditing mechanism every 3 years. All HCPs certified in the ESA APPRISE Oncology Program will be required to retrain and re-enroll during a 1-year re-enrollment phase beginning at the 3-year anniversary of the implementation of the ESA APPRISE Oncology Program. Upon completion of retraining and re-enrollment, the HCP will maintain the same ESA APPRISE Oncology Program enrollment number. Failure to re-enroll will result in suspension of access to Epogen/Procrit.

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

iv. Ensure that printed copies of the Epogen/Procrit Medication Guides are available upon request through the ESA APPRISE Oncology Program Call Center.

v. Ensure that, as part of the enrollment process, HCPs receive the following materials that are part of the ESA APPRISE Oncology Program and are appended to this REMS:

- ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers
- ESA APPRISE Oncology Program Training Module for Healthcare Providers
- ESA APPRISE Oncology Program Healthcare Provider Flashcard

- Epogen/Procrit Medication Guides
- The ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form
- HCP Program Starter Kit

2. Healthcare providers who prescribe Epogen/Procrit for patients with cancer in hospitals are specially certified.

a. Amgen will ensure that appropriately licensed HCPs who prescribe Epogen/Procrit for patients with cancer in hospitals are certified.

b. To become specially certified, HCPs must enroll into the ESA APPRISE Oncology Program by doing the following:

i. Review the full prescribing information which includes the Medication Guide.

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 provide and review the Medication Guide with the oncology patient or patient representative at the initiation of each new course of ESA therapy. After initiation of treatment, and for as long as treatment continues, provide an Epogen/Procrit Medication Guide to each oncology patient once a month during regular office visits—or, if regular office visits occur less frequently than once a month, at the next regularly scheduled office visit.

v. Agree to send a completed signed copy of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms, which may be archived electronically through an electronic medical record system as long as they are retrievable.

c. Amgen will:

i. Provide each enrolled HCP a unique ESA APPRISE Oncology Program enrollment number, which will be used to confirm enrollment in the Program.

ii. Ensure that HCPs retrain and re-enroll into the ESA APPRISE Oncology Program every 3 years, and re-enrollment will be evaluated by a comprehensive auditing mechanism every 3 years. All HCPs

certified in the ESA APPRISE Oncology Program will be required to retrain and re-enroll during a 1-year re-enrollment phase beginning at the 3-year anniversary of the implementation of the ESA APPRISE Oncology Program. Upon completion of retraining and re-enrollment, the HCP will maintain the same ESA APPRISE Oncology Program enrollment number. Failure to re-enroll will result in suspension of access to Epogen/Procrit.

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

iv. Ensure that printed copies of the Epogen/Procrit Medication Guides are available upon request through the ESA APPRISE Oncology Program Call Center.

v. Ensure that, as part of the enrollment process, HCPs receive the following materials that are part of the ESA APPRISE Oncology Program and are appended to this REMS:

- ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers
- ESA APPRISE Oncology Program Training Module for Healthcare Providers
- ESA APPRISE Oncology Program Healthcare Provider Flashcard
- Epogen/Procrit Medication Guides
- The ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form

3. Hospitals that dispense Epogen/Procrit for patients with cancer are specially certified.

a. Amgen will ensure that hospitals that dispense Epogen/Procrit are certified through the hospital *site level enrollment* in the ESA APPRISE Oncology Program.

b. 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 their hospital.

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:

i. Epogen/Procrit is only dispensed to patients with cancer after verifying:

- that the healthcare provider who prescribed Epogen/Procrit for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
- the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of Epogen/Procrit therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form prior to initiation of each new course of Epogen/Procrit therapy.

ii. If an HCP that prescribes Epogen/Procrit is not enrolled in the ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe Epogen/Procrit for patients with cancer.

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

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

- a list of each healthcare provider in my hospital who prescribes Epogen/Procrit for cancer patients
- documentation (ie, unique enrollment ID number) that each HCP in my hospital who prescribes Epogen/Procrit for patients with cancer is enrolled in the ESA APPRISE Oncology Program
- documentation of the risk:benefit discussion between certified prescriber and patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form for each cancer patient for whom an Epogen/Procrit prescription was filled

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

c. Amgen will:

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

ii. Ensure hospitals retrain and re-enroll into the ESA APPRISE Oncology Program every 3 years, and re-enrollment will be evaluated by a comprehensive auditing mechanism every 3 years. All hospitals certified in the ESA APPRISE Oncology Program will be required to retrain and re-enroll during a 1-year re-enrollment phase beginning at the 3-year anniversary of the implementation of the ESA APPRISE Oncology Program. Upon completion of retraining and re-enrollment, the hospital will maintain the same ESA APPRISE Oncology Program enrollment number. Failure to re-enroll will result in suspension of access to Procrit/Epogen for that hospital.

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 and are appended to this REMS:

- ESA APPRISE Oncology Program Enrollment Form for Hospitals
- ESA APPRISE Oncology Program Training Module for Hospital Designees
- ESA APPRISE Oncology Program Hospital Process Overview Flashcard
- HCP Program Starter Kit

4. Epogen/Procrit will be dispensed to patients with cancer with evidence or other documentation of safe-use conditions.

Amgen will ensure that certified hospitals and certified HCPs agree to only dispense Epogen/Procrit to patients with cancer once the risk:benefit discussion has occurred and the patient has signed a statement with their certified HCP (the ESA APPRISE Oncology Program Patient and Healthcare Professional [HCP] Acknowledgment Form) prior to the initiation of a new course of ESA therapy.

The ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form is part of the REMS and is appended.

D. Implementation System

The Implementation System includes the following:

1. Amgen will monitor compliance with documentation of the risk:benefit discussion and completion of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form and will work to improve implementation of these elements if non-compliance is identified.

    a. Amgen will allow certain changes to the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) 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 Acknowledgment and Healthcare Professional sections of the form cannot be changed. No content can be added or removed from these sections.

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

    b. The ESA APPRISE Oncology Program will conduct monitoring of all private practice-based clinics to determine compliance rates (ie, the number of patient- and HCP-signed Acknowledgment Forms returned to the ESA APPRISE Oncology Program Call Center compared to the number of patients initiating a new course of ESA therapy based on the amount of ESAs purchased) with section II.C.1 of this REMS and identify those HCPs in clinics with the poorest compliance rates. The ESA APPRISE Oncology Program will identify and audit at least 10% of the least compliant private-practice clinics with certified HCPs who prescribe ESAs to patients with cancer in the U.S. The private practice-based clinics will be audited by the ESA APPRISE Oncology Program to demonstrate evidence of compliance with the program including:

        i. That the number of ESA prescribers who prescribe ESAs 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 number).

        ii. That the number of patient- and HCP-signed Acknowledgment Forms returned to the ESA APPRISE Oncology Program Call

Center is not less than the number of patients initiating a new course of ESA therapy. For the audits to be effective, private practiced based clinics will implement a means to determine the total number of individual patients that received Epogen/Procrit based on orders and prescriptions written.

iii. Each audit will be conducted according to a time schedule that allows these data to be provided with each REMS assessment.

c. For hospitals, the ESA APPRISE Oncology Program will identify a random sample of certified hospitals enrolled in accordance with section II.C.3 of this REMS (at least 25). These hospitals will be audited by the ESA APPRISE Oncology Program to demonstrate evidence of compliance with the Program including:

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 number).

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

iii. For sites that are non-compliant, the ESA APPRISE Oncology Program will evaluate the reasons for non-compliance.

iv. The audits will be conducted according to a time schedule that allows these data to be provided with each REMS assessment.

2. Amgen will ensure that distributors will not 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 is certified under Section II.C.3 or the HCP is certified under Section II.C.1 or that certification is not applicable (ie, that the hospital does not dispense an ESA for patients with cancer or that the HCP does not prescribe and dispense an ESA for patients with cancer in a private practice setting).

3. Amgen will monitor HCP enrollment under II.C.1. on an ongoing basis to evaluate compliance with the ESA APPRISE Oncology Program enrollment requirements and will work to improve implementation of this element.

4. Amgen will monitor hospital enrollment under II.C.3 on an ongoing basis to evaluate compliance with the ESA APPRISE Oncology Program enrollment requirements and will work to improve implementation of this element.

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

E. 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 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.

MEDICATION GUIDE

Epogen® (Ee-po-jen)
(epoetin alfa)

Read this Medication Guide:

- before you start Epogen.
- if you are told by your healthcare provider that there is new information about Epogen.
- if you are told by your healthcare provider that you may inject Epogen at home, read this Medication Guide each time you receive a new supply of medicine.

This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Talk with your healthcare provider regularly about the use of Epogen and ask if there is new information about Epogen.

What is the most important information I should know about Epogen?

Using Epogen can lead to death or other serious side effects.

For patients with cancer:

Your healthcare provider has received special training through the ESA APPRISE Oncology Program in order to prescribe Epogen. Before you can begin to receive Epogen, you must sign the patient-healthcare provider acknowledgment form. When you sign this form, you are stating that your healthcare provider talked with you about the risks of taking Epogen.

These risks include that your tumor may grow faster and you may die sooner if you choose to take Epogen.

You should talk with your healthcare provider about:

- Why Epogen treatment is being prescribed for you.
- What are the chances you will get red blood cell transfusions if you do not take Epogen.
- What are the chances you will get red blood cell transfusions even if you take Epogen.
- How taking Epogen may affect the success of your cancer treatment.

After you have finished your chemotherapy course, Epogen treatment should be stopped.

For all patients who take Epogen, including patients with cancer or chronic kidney disease:

- If you decide to take Epogen, your healthcare provider should prescribe the smallest dose of Epogen that is needed to reduce your chance of getting red blood cell transfusions.
- You may get serious heart problems such as heart attack, stroke, heart failure, and may die sooner if you are treated with Epogen to reach a normal or near-normal hemoglobin level.
- You may get blood clots at any time while taking Epogen. If you are receiving Epogen for any reason and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus).

Call your healthcare provider or get medical help right away if you have any of these symptoms of blood clots:

- Chest pain
- Trouble breathing or shortness of breath
- Pain in your legs, with or without swelling

- A cool or pale arm or leg
- Sudden confusion, trouble speaking, or trouble understanding others' speech
- Sudden numbness or weakness in your face, arm, or leg, especially on one side of your body
- Sudden trouble seeing
- Sudden trouble walking, dizziness, loss of balance or coordination
- Loss of consciousness (fainting)
- Hemodialysis vascular access stops working

See **"What are the possible side effects of Epogen?"** below.

What is Epogen?

Epogen is a man-made form of the protein human erythropoietin that is given to reduce or avoid the need for red blood cell transfusions. Epogen stimulates your bone marrow to make more red blood cells. Having more red blood cells raises your hemoglobin level. If your hemoglobin level stays too high or if your hemoglobin goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen even if you take Epogen and do not have an increase in your hemoglobin level.

Epogen may be used to treat a lower than normal number of red blood cells (anemia) if it is caused by:

- Chronic kidney disease (you may or may not be on dialysis).
- Chemotherapy that will be used for at least two months after starting Epogen.
- A medicine called zidovudine (AZT) used to treat HIV infection.

Epogen may also be used to reduce the chance you will need red blood cell transfusions if you are scheduled for certain surgeries where a lot of blood loss is expected.

Epogen should not be used for treatment of anemia:

- If you have cancer and you will not be receiving chemotherapy that may cause anemia for at least 2 more months.
- If you have a cancer that has a high chance of being cured.
- In place of emergency treatment for anemia (red blood cell transfusions).

Epogen has not been proven to improve quality of life, fatigue, or well-being.

Epogen should not be used to reduce the chance of red blood cell transfusions if:

- You are scheduled for surgery on your heart or blood vessels
- You are able and willing to donate blood prior to surgery

Who should not take Epogen?

Do not take Epogen if you:

- Have cancer and have not been counseled by your healthcare provider regarding the risks of Epogen or if you have not signed the patient-healthcare provider acknowledgment form before you start Epogen treatment.
- Have high blood pressure that is not controlled (uncontrolled hypertension).
- Have been told by your healthcare provider that you have or have ever had a type of anemia called Pure Red Cell Aplasia (PRCA) that starts after treatment with Epogen or other erythropoietin protein medicines.
- Have had a serious allergic reaction to Epogen.

Do not give Epogen from multidose vials to:

- Pregnant or breastfeeding women

- Babies

What should I tell my healthcare provider before taking Epogen?

Epogen may not be right for you. **Tell your healthcare provider about all your health conditions,** including if you:

- Have heart disease.
- Have high blood pressure.
- Have had a seizure (convulsion) or stroke.
- Have any other medical conditions.
- Are pregnant or planning to become pregnant. It is not known if Epogen may harm your unborn baby. Talk to your healthcare provider about possible pregnancy and birth control choices that are right for you. If you are pregnant, discuss with your healthcare provider about enrolling in Amgen's Pregnancy Surveillance Program or call 1-800-772-6436 (1-800-77-AMGEN).
- Are breast-feeding or planning to breast-feed. It is not known if Epogen passes into breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you and show it to your healthcare provider when you get a new medicine.

How should I take Epogen?

See **"What is the most important information I should know about Epogen?"**

For patients with cancer:

Before you begin to receive Epogen, your healthcare provider will:

- Ask you to review this Epogen Medication Guide.
- Explain the risks of Epogen and answer all your questions about Epogen.
- Have you sign the patient-healthcare provider acknowledgment form.

For all patients who take Epogen:

- Continue to follow your healthcare provider's instructions for diet and medicines, including medicines for high blood pressure, while taking Epogen.
- Have your blood pressure checked as instructed by your healthcare provider.
- If you or your caregiver has been trained to give Epogen shots (injections) at home:
  - Be sure that you read, understand, and follow the "Instructions for Use" that come with Epogen.
  - Take Epogen exactly as your healthcare provider tells you to. Do not change the dose of Epogen unless told to do so by your healthcare provider.
  - Your healthcare provider will show you how much Epogen to use, how to inject it, how often it should be injected, and how to safely throw away the used vials, syringes, and needles.
  - If you miss a dose of Epogen, call your healthcare provider right away and ask what to do.
  - If you take more than the prescribed amount of Epogen, call your healthcare provider right away.

What are the possible side effects of Epogen?

Epogen may cause serious side effects.

- See **"What is the most important information I should know about Epogen?"**

- **High blood pressure.** High blood pressure is a common side effect of Epogen in patients with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medicine while taking Epogen. This can happen even if you have never had high blood pressure before. Your healthcare provider should check your blood pressure often. If your blood pressure does go up, your healthcare provider may prescribe new or more blood pressure medicine.
- **Seizures.** If you have any seizures while taking Epogen, get medical help right away and tell your healthcare provider.
- **Antibodies to Epogen.** Your body may make antibodies to Epogen. These antibodies can block or lessen your body's ability to make red blood cells and cause you to have severe anemia. Call your healthcare provider if you have unusual tiredness, lack of energy, dizziness, or fainting. You may need to stop taking Epogen.
- **Serious allergic reactions.** Serious allergic reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness and fainting because of a drop in blood pressure, swelling around your mouth or eyes, fast pulse, or sweating. If you have a serious allergic reaction, stop using Epogen and call your healthcare provider or get medical help right away.
- **Dangers of giving Epogen to newborns, infants, and pregnant or breastfeeding women.** Do not use Epogen from multi-dose vials in newborns, infants, pregnant or breastfeeding women because the Epogen in these vials contains benzyl alcohol. Benzyl alcohol has been shown to cause brain damage, other serious side effects, and death in newborn and premature babies. Epogen that comes in single-dose vials does not contain benzyl alcohol. **See "Who should not take Epogen?"**

Common side effects of Epogen include:

- joint, muscle, or bone pain
- fever
- cough
- rash
- nausea
- vomiting
- soreness of mouth
- itching
- headache
- redness and pain in the skin where Epogen shots were given

These are not all of the possible side effects of Epogen. Your healthcare provider can give you a more complete list. Tell your healthcare provider about any side effects that bother you or that do not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Epogen?

- Do not shake Epogen.
- Protect Epogen from light.
- Store Epogen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze Epogen.** Do not use Epogen that has been frozen.
- Throw away multidose vials of Epogen no later than 21 days from the first day that you put a needle into the vial.
- Single-dose vials of Epogen should be used only one time. Throw the vial away after use even if there is medicine left in the vial.

Keep Epogen and all medicines out of the reach of children.

General information about Epogen

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use Epogen only for the condition for which it has been prescribed. Do not give Epogen to other patients even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Epogen. If you would like more information about Epogen, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about Epogen that is written for healthcare professionals. For more information, go to the following website: www.epogen.com or call 1-800-77-AMGEN.

What are the ingredients in Epogen?

Active Ingredient: epoetin alfa

Inactive Ingredients:

- Multidose vials contain benzyl alcohol.
- All vials contain albumin (human), sodium citrate, sodium chloride, and citric acid.
- Single-dose vials containing 40,000 Units of Epogen also contain sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrate.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

AMGEN®

Manufactured by:

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MEDICATION GUIDE

PROCRIT® (PRO′–KRIT)
(epoetin alfa)

Read this Medication Guide:

- before you start PROCRIT.
- if you are told by your healthcare provider that there is new information about PROCRIT.
- if you are told by your healthcare provider that you may inject PROCRIT at home, read this Medication Guide each time you receive a new supply of medicine.

This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Talk with your healthcare provider regularly about the use of PROCRIT and ask if there is new information about PROCRIT.

What is the most important information I should know about PROCRIT?

Using PROCRIT can lead to death or other serious side effects.

For patients with cancer:

Your healthcare provider has received special training through the ESA APPRISE Oncology Program in order to prescribe PROCRIT. Before you can begin to receive PROCRIT, you must sign the patient-healthcare provider acknowledgment form. When you sign this form, you are stating that your healthcare provider talked with you about the risks of taking PROCRIT.

These risks include that your tumor may grow faster and you may die sooner if you choose to take PROCRIT.

You should talk with your healthcare provider about:

- Why PROCRIT treatment is being prescribed for you.
- What are the chances you will get red blood cell transfusions if you do not take PROCRIT.
- What are the chances you will get red blood cell transfusions even if you take PROCRIT.
- How taking PROCRIT may affect the success of your cancer treatment.

After you have finished your chemotherapy course, PROCRIT treatment should be stopped.

For all patients who take PROCRIT, including patients with cancer or chronic kidney disease:

- If you decide to take PROCRIT, your healthcare provider should prescribe the smallest dose of PROCRIT that is needed to reduce your chance of getting red blood cell transfusions.
- You may get serious heart problems such as heart attack, stroke, heart failure, and may die sooner if you are treated with PROCRIT to reach a normal or near-normal hemoglobin level.
- You may get blood clots at any time while taking PROCRIT. If you are receiving PROCRIT for any reason and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus).

Call your healthcare provider or get medical help right away if you have any of these symptoms of blood clots:

- Chest pain

- Trouble breathing or shortness of breath
- Pain in your legs, with or without swelling
- A cool or pale arm or leg
- Sudden confusion, trouble speaking, or trouble understanding others' speech
- Sudden numbness or weakness in your face, arm, or leg, especially on one side of your body
- Sudden trouble seeing
- Sudden trouble walking, dizziness, loss of balance or coordination
- Loss of consciousness (fainting)
- Hemodialysis vascular access stops working

See **"What are the possible side effects of PROCRIT ?"** below.

What is PROCRIT?

PROCRIT is a man-made form of the protein human erythropoietin that is given to reduce or avoid the need for red blood cell transfusions. PROCRIT stimulates your bone marrow to make more red blood cells. Having more red blood cells raises your hemoglobin level. If your hemoglobin level stays too high or if your hemoglobin goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen even if you take PROCRIT and do not have an increase in your hemoglobin level.

PROCRIT may be used to treat a lower than normal number of red blood cells (anemia) if it is caused by:

- Chronic kidney disease (you may or may not be on dialysis).
- Chemotherapy that will be used for at least two months after starting PROCRIT.
- A medicine called zidovudine (AZT) used to treat HIV infection.

PROCRIT may also be used to reduce the chance you will need red blood cell transfusions if you are scheduled for certain surgeries where a lot of blood loss is expected.

PROCRIT should not be used for treatment of anemia:

- If you have cancer and you will not be receiving chemotherapy that may cause anemia for at least 2 more months.
- If you have a cancer that has a high chance of being cured.
- In place of emergency treatment for anemia (red blood cell transfusions).

PROCRIT has not been proven to improve quality of life, fatigue, or well-being.

PROCRIT should not be used to reduce the chance of red blood cell transfusions if:
- You are scheduled for surgery on your heart or blood vessels
- You are able and willing to donate blood prior to surgery

Who should not take PROCRIT?

Do not take PROCRIT if you:

- Have cancer and have not been counseled by your healthcare provider regarding the risks of PROCRIT or if you have not signed the patient-healthcare provider acknowledgment form before you start PROCRIT treatment.
- Have high blood pressure that is not controlled (uncontrolled hypertension).
- Have been told by your healthcare provider that you have or have ever had a type of anemia called Pure Red Cell Aplasia (PRCA) that starts after treatment with PROCRIT or other erythropoietin protein medicines.

- Have had a serious allergic reaction to PROCRIT.

Do not give PROCRIT from multidose vials to:
- Pregnant or breastfeeding women
- Babies

What should I tell my healthcare provider before taking PROCRIT?

PROCRIT may not be right for you. **Tell your healthcare provider about all your health conditions,** including if you:

- Have heart disease.
- Have high blood pressure.
- Have had a seizure (convulsion) or stroke.
- Have any other medical conditions.
- Are pregnant or planning to become pregnant. It is not known if PROCRIT may harm your unborn baby. Talk to your healthcare provider about possible pregnancy and birth control choices that are right for you.
- Are breast-feeding or planning to breast-feed. It is not known if PROCRIT passes into breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you and show it to your healthcare provider when you get a new medicine.

How should I take PROCRIT?

See **"What is the most important information I should know about PROCRIT?"**

For patients with cancer:

Before you begin to receive PROCRIT, your healthcare provider will:

- Ask you to review this PROCRIT Medication Guide.
- Explain the risks of PROCRIT and answer all your questions about PROCRIT.
- Have you sign the patient-healthcare provider acknowledgment form.

For all patients who take PROCRIT:

- Continue to follow your healthcare provider's instructions for diet and medicines, including medicines for high blood pressure, while taking PROCRIT.
- Have your blood pressure checked as instructed by your healthcare provider.
- If you or your caregiver has been trained to give PROCRIT shots (injections) at home:
  - Be sure that you read, understand, and follow the "Instructions for Use" that come with PROCRIT.
  - Take PROCRIT exactly as your healthcare provider tells you to. Do not change the dose of PROCRIT unless told to do so by your healthcare provider.
  - Your healthcare provider will show you how much PROCRIT to use, how to inject it, how often it should be injected, and how to safely throw away the used vials, syringes, and needles.
  - If you miss a dose of PROCRIT, call your healthcare provider right away and ask what to do.
  - If you take more than the prescribed amount of PROCRIT , call your healthcare provider right away.

What are the possible side effects of PROCRIT?

PROCRIT may cause serious side effects.

- See **"What is the most important information I should know about PROCRIT?"**

- **High blood pressure.** High blood pressure is a common side effect of PROCRIT in patients with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medicine while taking PROCRIT. This can happen even if you have never had high blood pressure before. Your healthcare provider should check your blood pressure often. If your blood pressure does go up, your healthcare provider may prescribe new or more blood pressure medicine.
- **Seizures.** If you have any seizures while taking PROCRIT, get medical help right away and tell your healthcare provider.
- **Antibodies to PROCRIT.** Your body may make antibodies to PROCRIT . These antibodies can block or lessen your body's ability to make red blood cells and cause you to have severe anemia. Call your healthcare provider if you have unusual tiredness, lack of energy, dizziness, or fainting. You may need to stop taking PROCRIT.
- **Serious allergic reactions.** Serious allergic reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness and fainting because of a drop in blood pressure, swelling around your mouth or eyes, fast pulse, or sweating. If you have a serious allergic reaction, stop using PROCRIT and call your healthcare provider or get medical help right away.
- **Dangers of giving PROCRIT to newborns, infants, and pregnant or breastfeeding women.** Do not use PROCRIT from multi-dose vials in newborns, infants, pregnant or breastfeeding women because the PROCRIT in these vials contains benzyl alcohol. Benzyl alcohol has been shown to cause brain damage, other serious side effects, and death in newborn and premature babies. PROCRIT that comes in single-dose vials does not contain benzyl alcohol. **See "Who should not take PROCRIT?"**

Common side effects of PROCRIT include:

- joint, muscle, or bone pain
- fever
- cough
- rash
- nausea
- vomiting
- soreness of mouth
- itching
- headache
- redness and pain in the skin where PROCRIT shots were given

These are not all of the possible side effects of PROCRIT. Your healthcare provider can give you a more complete list. Tell your healthcare provider about any side effects that bother you or that do not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PROCRIT?

- Do not shake PROCRIT.
- Protect PROCRIT from light.
- Store PROCRIT in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze PROCRIT.** Do not use PROCRIT that has been frozen.
- Throw away multidose vials of PROCRIT no later than 21 days from the first day that you put a needle into the vial.

- Single-dose vials of PROCRIT should be used only one time. Throw the vial away after use even if there is medicine left in the vial.

Keep PROCRIT and all medicines out of the reach of children.

General information about PROCRIT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use PROCRIT only for the condition for which it has been prescribed. Do not give PROCRIT to other patients even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about PROCRIT. If you would like more information about PROCRIT, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about PROCRIT that is written for healthcare professionals. For more information, go to the following website: www.PROCRIT.com or call 1-800-JANSSEN (1-800-526-7736).

What are the ingredients in PROCRIT?

Active Ingredient: epoetin alfa

Inactive Ingredients:
- Multidose vials contain benzyl alcohol.
- All vials contain albumin (human), sodium citrate, sodium chloride, and citric acid.
- Single-dose vials containing 40,000 Units of PROCRIT also contain sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrate.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799 U.S.A.

Manufactured for:

Janssen Products, LP
Horsham, Pennsylvania 19044

Printed in U. S. A.

Revised: 05/2012

Name
Address
City, State Zip

[Date]

Re: IMPORTANT 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 prescribe, or prescribe and dispense, ESAs to patients with cancer. In order to continue to obtain ESAs through distributors for use in clinics or to prescribe ESAs for hospitalized patients, you must train and enroll in the ESA APPRISE Oncology Program at www.esa-apprise.com no later than [insert 90 day enrollment date] or your ability to obtain ESAs for patients with cancer will be suspended.

As you may be aware, on 16 February 2010, the ESA APPRISE Oncology Program was approved by the FDA as part of a Risk Evaluation and Mitigation Strategy (REMS) for ESAs. The FDA has determined that a 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**.

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. An ESA REMS Flashcard is enclosed to provide a summary of the ESA REMS.

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® full prescribing information, including **Boxed WARNINGS**, and Medication Guides.

Sincerely,

Amgen
Janssen Products, LP

Enclosure:
ESA REMS Flashcard

Name
Address
City, State Zip

[Date]

Re: IMPORTANT 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 through distributors, your hospital must designate a representative (e.g., Pharmacy Director or Head of Hematology/Oncology) who, as the Hospital Designee, must train and enroll in the ESA APPRISE Oncology Program at www.esa-apprise.com by [insert 90 day enrollment date] or your hospital's ability to obtain ESAs to dispense to patients with cancer will be suspended.

As you may be aware, on 16 February 2010, the ESA APPRISE Oncology Program was approved by the FDA as part of a Risk Evaluation and Mitigation Strategy (REMS) for ESAs. The FDA has determined that a 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**.

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. An ESA REMS Flashcard is enclosed to provide a summary of the ESA REMS.

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Sincerely,

Amgen
Janssen Products, LP

Enclosure:
ESA REMS Flashcard

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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 Update Screenshots

May 16, 2012

Version 3.0.02

Table of Contents

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 FDA determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the decision to initiate treatment with an ESA is informed by a discussion between the patient and healthcare provider (HCP) about the benefits and risks associated with ESA therapy.*

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

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

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

Key Program Requirements

Healthcare Providers	Hospitals
1. Complete Training	**1a. Select a Hospital Designee** **1b. Complete Training**
2. Enroll in the ESA APPRISE Oncology Program	**2. Enroll in the ESA APPRISE Oncology Program**
3. Inform • Provide the Medication Guide to patient • Conduct the risk:benefit discussion with the patient and document this has occurred by completing and signing the Patient Acknowledgment Form	**3. Implement** • Hospital Designee establishes and oversees measures designed to ensure ESA prescribers adhere to the ESA APPRISE Oncology Program requirements in the hospital setting

For further details on the program requirements, see the ESA APPRISE Oncology Program Overview page.

Note that patient registration or approval through the ESA APPRISE Oncology Program is not required.

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

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 ESA therapy in patients on cancer chemotherapy only if the hemoglobin is less than 10 g/dL.
- Use the lowest dose needed to avoid red blood cell (RBC) transfusions.
- Discontinue ESA treatment following completion of a chemotherapy course.

Questions about the ESA APPRISE Oncology Program?

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

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

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

Janssen

AMGEN Oncology

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.

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

ESA APPRISE Oncology Program Overview

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

1. REMS goals

- To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Aranesp® or Epogen®/Procrit® by educating them on the risks of Aranesp® or Epogen®/Procrit®.
- For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE Oncology Program, is to mitigate the risk of shortened overall survival and/or increased risk of tumor progression or recurrence.

2. Program key requirements

- **TRAIN**
  Complete the ESA APPRISE Oncology Program training, which includes a review of the risks of ESA therapy and appropriate use of ESAs in patients with cancer.
- **ENROLL**
  Enroll in the ESA APPRISE Oncology Program by completing the ESA APPRISE Oncology Program Enrollment Form for Healthcare Providers.
- **INFORM**
  Prior to each new course of ESA therapy:
  - Provide and review the appropriate Medication Guide and counsel each patient on the risks and benefits of ESAs. Review ESA risk:benefit information with your patient, and answer any questions he/she may have.
  - Document that the ESA risk:benefit discussion occurred using the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form. Fill in your ESA APPRISE enrollment ID number and ensure both you and your patient sign the form.
  - If you are in a private practice setting, send the form (or modified version consistent with the allowable changes) by facsimile to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124 or mail using the prepaid envelope to P.O. Box #29000, Phoenix, AZ 85038 and retain an archival copy of the form.
  - If you are in a hospital setting, provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

3. Repercussions of failing to train and enroll and re-enroll at 3 years

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

Continue to the ESA APPRISE Oncology Program Training & Enrollment section now.

Welcome to the ESA APPRISE Oncology Program

What is the ESA APPRISE Oncology Program?

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Begin Training & Enrollment ×

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

○ Yes ○ No

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clinical studies in patients with cancer treated with ESAs.

Key Program Requirements

Healthcare Providers	Hospitals
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Begin Training & Enrollment

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

○ Yes ◉ No

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

Non-prescribing HCPs—Training only (click here)

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Amgen and Janssen Products, LP have implemented the ESA APPRISE (Assisting Providers and cancer Patients with Risk information for the Safe use of ESAs) Oncology Program as part of a REMS designed for H

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

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Key Program Requirements

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Note that patient registration or approval through the ESA APPRISE Oncology Program is not required.

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

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 ESA therapy in patients on cancer chemotherapy only if the hemoglobin is less than 10 g/dL.
- Use the lowest dose needed to avoid red blood cell (RBC) transfusions.
- Discontinue ESA treatment following completion of a chemotherapy course.

Questions about the ESA APPRISE Oncology Program?

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

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

*Additional information on REMS may be found at www.FDA.gov

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

ESA APPRISE Training Module for Healthcare Providers

This 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 Training Module is the core requirement for enrollment within the ESA APPRISE Oncology Program, developed by Amgen and Janssen Products, LP. The ESA APPRISE Oncology Program is part of a Risk Evaluation and Mitigation Strategy (REMS). The Food and Drug Administration (FDA) has determined that a 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 shown in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

This training module is intended for HCPs who prescribe or prescribe and dispense ESAs for patients with cancer.

The goals of the REMS for Aranesp® and Epogen®/Procrit® are:

- To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Aranesp® or Epogen®/Procrit® by educating them on the risks of Aranesp® or Epogen®/Procrit®.
- For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE Oncology Program, is to mitigate the risk of shortened overall survival and/or increased risk of tumor progression or recurrence.

FAILURE TO ENROLL IN THE ESA APPRISE ONCOLOGY PROGRAM 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® to cancer patients.

The ESA APPRISE Oncology Program Training Module features four sections:

Section 1: Key safety information for the use of ESAs in 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® full prescribing information, including **Boxed WARNINGS**, and Medication Guides.

Click the next button to continue

Training & Enrollment Progress

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

1. **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	Achieved Hemoglobin (Median Q1, Q3)	Primary Endpoint	Adverse Outcome for ESA-containing Arm
Chemotherapy				
Cancer 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
Cancer Study 2 Lymphoid malignancy (n=344)	13–15 g/dL (M) 13–14 g/dL (F)	11.0 g/dL 9.8, 12.1 g/dL	Proportion of patients achieving a hemoglobin response	Decreased overall survival
Cancer 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 yr. relapse-free and overall survival
Cancer 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 yr. progression-free and overall survival and locoregional control
Radiotherapy Alone				
Cancer 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 survival Decreased overall survival
Cancer 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				
Cancer Study 7 Non–small cell lung cancer (n=70)	12–14 g/dL	Not available	Quality of life	Decreased overall survival
Cancer 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

2. **ESAs increase the risk of serious cardiovascular and thromboembolic reactions.**

An increased incidence of thromboembolic reactions, some serious and life-threatening, occurred in patients with cancer treated with ESAs. In a randomized, placebo-controlled study (Cancer Study 1) 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. Based on Kaplan-Meier estimates, at the time of study termination, the 12-month survival was lower in the epoetin alfa group than in the placebo group (70% vs. 76%; HR 1.37, 95% CI: 1.07, 1.75; p = 0.012).

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

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

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 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.

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

Section 3: Program Requirements and Materials for Healthcare Providers

HCP requirements for patient education and counseling:

The ESA APPRISE Oncology Program requires HCPs to educate and counsel patients utilizing these program materials in the following manner:

- Provide the appropriate ESA Medication Guide to each patient prior to each new course of ESA therapy, review its contents, and counsel each patient on the risks and benefits of ESAs.
- Inform each patient that ESAs are associated with the following risks: increased mortality, serious cardiovascular and thromboembolic reactions, and increased risk of tumor progression or recurrence.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with the patient has occurred by completing and signing the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form.

CLICK HERE

- In a private practice-based setting, return the form (or modified version consistent with the allowable changes) via mail or fax (preferred method) to the ESA APPRISE Oncology Program Call Center as instructed on the acknowledgment form; maintain a copy of the signed ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form on-site.
- If you are in a hospital setting, provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.
- To learn more about allowed changes to the Patient Acknowledgment Form, please refer to the Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics flashcard.

CLICK HERE

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

A re-enrollment period will occur every 3 years for this program. You will be notified when re-enrollment is required.

Upon completion of this enrollment process you will receive an ESA APPRISE Oncology Program enrollment identification (ID) number via email. Your enrollment ID number will be required on every patient acknowledgment form.

Once you have enrolled, you will receive the HCP Program Starter Kit to assist you in implementing the ESA APPRISE Oncology Program. The HCP Program Starter Kit will be shipped to each private practice location listed on your enrollment form.

Materials provided in the HCP Program Starter Kit:

- ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form
- Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) Medication Guides
- Prepaid Reply Envelopes
- Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics

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

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

Yes, I have reviewed all of Section 3

Section 4: Healthcare Provider Enrollment

Now that you have completed the ESA APPRISE Oncology Program Training Module, you are ready to enroll. Enrollment confirms the fact that you have reviewed the safety and appropriate use information for ESAs in 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, including enrollment, will result in suspension of your access to ESAs.

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

Training & Enrollment Progress

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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 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 ESAs increased the risk of death from cardiovascular and thromboembolic reactions in clinical studies in patients with cancer treated with ESAs.
- I understand that in order to decrease these risks, the lowest dose of ESAs should be used to avoid red blood cell 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 of treatment.

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®.

When I prescribe and dispense an ESA to a patient with cancer in my clinic, when an ESA is dispensed for administration under my supervision to a patient with cancer in an infusion center, or when I prescribe or order an ESA for a patient with cancer in a hospital:	I will provide an Aranesp® or Epogen®/Procrit® Medication Guide to each oncology patient at the initiation of each new course of the respective ESA therapy. After initiation of treatment, and for as long as treatment continues, I will provide the appropriate Aranesp® or Epogen®/Procrit® Medication Guide to each oncology patient once a month during regular office visits—or, if regular office visits occur less frequently than once a month, at the next regularly scheduled office visit.

- I will review the contents of the respective Medication Guide with the patient, counsel each patient on the risks (increased mortality, serious cardiovascular and thromboembolic reactions, and increased risk of tumor progression or recurrence) and benefits of Aranesp® or Epogen®/Procrit® I am prescribing to my patient before each new course of the respective ESA therapy. I will document that the discussion with each patient has occurred by signing the ESA APPRISE Oncology Program Patient and Healthcare Professional Acknowledgment Form and by obtaining the patient's signature.
  - By signing the patient section of the form, the patient acknowledges the following:
    - I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:
      - I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
      - I have had all my questions or concerns about Aranesp® or Epogen®/Procrit® or my treatment answered by my healthcare professional.
      - I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots, and I may die sooner.
  - By signing the HCP section of the form, as a healthcare provider enrolled in the ESA APPRISE Oncology Program, I acknowledge that prior to prescribing my patient's first dose of Aranesp® or Epogen®/Procrit® therapy:
    - I provided my patient with the appropriate Aranesp® or Epogen®/Procrit® Medication Guide and instructed the patient to read it carefully before signing this form.
    - I counseled my patient on the risks and benefits of Aranesp® or Epogen®/Procrit®, using the respective Medication Guide as the review tool in counseling the patient.
    - I discussed all concerns and answered all questions my patient had about Aranesp® or Epogen®/Procrit® or his/her treatment to the best of my ability.
    - The patient signed the Acknowledgment Form in my presence.

When I 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 in an infusion center:	• I will send a signed copy of the ESA APPRISE Oncology Program Patient and Healthcare Professional Acknowledgment Form (or modified version consistent with the allowable changes) back to the ESA APPRISE Oncology Program Call Center and retain a copy for my records. • I agree that the ESA obtained for use in my patients with cancer will not be 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 ESA APPRISE Oncology Program Patient and Healthcare Professional Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.
• I will comply with any program monitoring and auditing required to assess the effectiveness of the ESA APPRISE Oncology Program.	

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

Training & Enrollment Progress

BACK NEXT

ESA APPRISE Oncology Program Enrollment for Prescribers

* indicates a required field.

Are you enrolling into the ESA APPRISE Oncology Program for the first time? *
- ○ First-time Enrollment
- ○ Re-enrollment

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)

Training & Enrollment Progress

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Reference ID: 3138387

ESA APPRISE Oncology Program Enrollment for Prescribers

* indicates a required field.

Are you enrolling into the ESA APPRISE Oncology Program for the first time? *
- ( ) First-time Enrollment
- (•) Re-enrollment

Enrollment ID *

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)

Training & Enrollment Progress

BACK NEXT

ESA APPRISE Oncology Program Enrollment for Prescribers

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

Training & Enrollment Progress

BACK NEXT

ESA APPRISE Oncology Program Enrollment for Prescribers

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

Training & Enrollment Progress

BACK NEXT

ESA APPRISE Oncology Program Enrollment for Prescribers

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

Your entered address:

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

Training & Enrollment Progress

BACK NEXT

ESA APPRISE Oncology Program Enrollment for Prescribers

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

Training & Enrollment Progress

BACK NEXT

ESA APPRISE Oncology Program Enrollment for Prescribers

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 Professional (HCP) 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 HCP Program Starter Kit which contains the required materials for the ESA APPRISE Oncology Program. The HCP Program Starter Kit will be shipped to each private practice location in the above list.

HCP Program Starter Kit
Materials provided in the HCP Program Starter Kit include:

- ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms
- Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit ® (epoetin alfa) Medication Guides
- Prepaid Reply Envelopes
- Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics

Until your starter kits arrive you can download and print the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form and begin completing the form with your patients.

For questions regarding the ESA APPRISE Oncology Program, please visit the ESA APPRISE Oncology Program Frequently Asked Questions page, 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 a reminder, patient registration or approval through the ESA APPRISE Oncology Program is not required.

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

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

ESA APPRISE Training Module for Hospital Designees

This 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 Training Module is the core requirement for enrollment within the ESA APPRISE Oncology Program, developed by Amgen and Janssen Products, LP. The ESA APPRISE Oncology Program is part of a Risk Evaluation and Mitigation Strategy (REMS). The Food and Drug Administration (FDA) has determined that a 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 shown in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

This training module is intended for Hospital Designees at hospitals that dispense ESAs for patients with cancer.

The goals of the REMS for Aranesp® and Epogen®/Procrit® are:

- To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Aranesp® or Epogen®/Procrit® by educating them on the risks of Aranesp® or Epogen®/Procrit®.
- For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program, is to mitigate the risk of shortened overall survival and/or increased risk of tumor progression or recurrence.

FAILURE TO ENROLL IN THE ESA APPRISE ONCOLOGY PROGRAM WILL RESULT IN SUSPENSION OF YOUR 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® to cancer patients as well as the requirements for Hospital Designees who must oversee this safety program at their respective Hospitals.

The ESA APPRISE Oncology Program Training Module features four sections:

Section 1: Key safety information for the use of ESAs in 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® full prescribing information, including **Boxed WARNINGS**, and Medication Guides.

Click the next button to continue

Training & Enrollment Progress

BACK NEXT

Reference ID: 3138387

Section 1: Key ESA Safety Information for Appropriate Use in Patients With Cancer

1. **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	Achieved Hemoglobin (Median Q1, Q3)	Primary Endpoint	Adverse Outcome for ESA-containing Arm
Chemotherapy				
Cancer 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
Cancer Study 2 Lymphoid malignancy (n=344)	13–15 g/dL (M) 13–14 g/dL (F)	11.0 g/dL 9.8, 12.1 g/dL	Proportion of patients achieving a hemoglobin response	Decreased overall survival
Cancer 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 yr. relapse-free and overall survival
Cancer 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 yr. progression-free and overall survival and locoregional control
Radiotherapy Alone				
Cancer 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 survival Decreased overall survival
Cancer 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				
Cancer Study 7 Non–small cell lung cancer (n=70)	12–14 g/dL	Not available	Quality of life	Decreased overall survival
Cancer 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

2. **ESAs increase the risk of serious cardiovascular and thromboembolic reactions.**

An increased incidence of thromboembolic reactions, some serious and life-threatening, occurred in patients with cancer treated with ESAs. In a randomized, placebo-controlled study (Cancer Study 1) 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. Based on Kaplan-Meier estimates, at the time of study termination, the 12-month survival was lower in the epoetin alfa group than in the placebo group (70% vs. 76%; HR 1.37, 95% CI: 1.07, 1.75; p = 0.012).

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

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

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 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.

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

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

HCP requirements for patient education and counseling:

The ESA APPRISE Oncology Program requires HCPs to educate and counsel patients utilizing these program materials in the following manner:

- Provide the appropriate ESA Medication Guide to each patient prior to each new course of ESA therapy, review its contents, and counsel each patient on the risks and benefits of ESAs.
- Inform each patient that ESAs are associated with the following risks: increased mortality, serious cardiovascular and thromboembolic reactions, and increased risk of tumor progression or recurrence.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with the patient has occurred by completing and signing the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form.

CLICK HERE

- In a private practice-based setting, return the form (or modified version consistent with the allowable changes) via mail or fax (preferred method) to the ESA APPRISE Oncology Program Call Center as instructed on the acknowledgment form; maintain a copy of the signed ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form on-site.
- If you are in a hospital setting, provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

Hospital Designee Requirements

- Assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in your hospital.
- Complete the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- Understand that if HCPs in your 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 ESAs for your hospital.
- Inform all Aranesp® or Epogen®/Procrit® prescribers at your hospital of the ESA APPRISE Oncology Program training and oncology prescriber certification requirements.
- Establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that, in your hospital:
  - ESAs are only dispensed to patients with cancer after verifying:
    - that the HCP who prescribed ESAs for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
    - that the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of ESA therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form prior to initiation of each new course of ESA therapy.
  - If an HCP who prescribes ESAs is not enrolled in the ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe ESAs for patients with cancer.
- Oversee compliance with program monitoring and auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
- Maintain evidence of compliance with the ESA APPRISE Oncology Program for monitoring and auditing purposes, as follows:
  - A list of each HCP in your hospital who prescribes ESAs for cancer patients
  - Documentation (i.e., unique enrollment ID number) that each HCP in your hospital who prescribes ESAs for patients with cancer is enrolled in the ESA APPRISE Oncology Program
  - Documentation of the risk:benefit discussion between certified prescriber and cancer patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form for each cancer patient for whom an ESA prescription was filled
- To learn more about allowed changes to the Patient Acknowledgment Form, please refer to the Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics flashcard.

CLICK HERE

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.

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

A re-enrollment period will occur every 3 years for this program. You will be notified when re-enrollment is required.

Upon completion of this enrollment process, you (and an alternate contact, if provided) will receive an email with the ESA APPRISE Oncology Program enrollment ID number unique to your hospital. This enrollment ID number allows you to identify HCPs enrolled at your location, by clicking the Hospital Designee log-in at the top right of the ESA APPRISE Oncology Program website home page. You can also order more ESA APPRISE Oncology Program materials via **www.esa-apprise.com** using the hospital enrollment ID number.

Once you have enrolled, you will receive the HCP Program Starter Kit to assist HCPs in your hospital in implementing the ESA APPRISE Oncology Program.

Materials provided in the HCP Program Starter Kit:

- ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form
- Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) Medication Guides
- Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics

The prescriber's enrollment identification number and the hospital's site identification number are required on every patient acknowledgment form.

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

Training & Enrollment Progress

Section 4: Hospital Designee Enrollment

Now that you 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 in patients with cancer, and commits you to complying with the program requirements.

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

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

Training & Enrollment Progress

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ESA APPRISE Oncology Program Enrollment for Hospitals

I agree to the following on behalf of my hospital:

- 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 my hospital.
- I have completed the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- I understand that if healthcare providers (HCPs) in my 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 my hospital.
- I will inform all Aranesp® or Epogen®/Procrit® prescribers at my hospital of the ESA APPRISE Oncology Program training and oncology prescriber certification requirements.
- I will establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that, in my hospital:
  - Aranesp® or Epogen®/Procrit® is only dispensed to patients with cancer after verifying:
    - that the HCP who prescribed Aranesp® or Epogen®/Procrit® for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
    - that the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of Aranesp or Epogen/Procrit therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) 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 ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
- I am authorized to oversee compliance with program monitoring and auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
- I will maintain evidence of compliance with the ESA APPRISE Oncology Program for monitoring and auditing purposes, as follows:
  - A list of each HCP in my hospital who prescribes Aranesp or Epogen/Procrit for cancer patients.
  - Documentation (ie, unique enrollment ID number) that each HCP in my hospital who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is enrolled in the ESA APPRISE Oncology Program.
  - Documentation of the risk:benefit discussion between certified prescriber and cancer patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional Acknowledgment Form for each cancer patient for whom an Aranesp or Epogen/Procrit prescription was filled.

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

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

Yes, I agree to all the above

Training & Enrollment Progress

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ESA APPRISE Oncology Program Enrollment For Hospitals

* indicates a required field.

Are you enrolling into the ESA APPRISE Oncology Program for the first time? *
- ○ First-time Enrollment
- ○ Re-enrollment

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 my hospital each time a new HCP affiliated with my hospital enrolls in the program. Note: You will automatically be notified of all HCPs 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)

Training & Enrollment Progress

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ESA APPRISE Oncology Program Enrollment For Hospitals

* indicates a required field.

Are you enrolling into the ESA APPRISE Oncology Program for the first time? *
- ( ) First-time Enrollment
- (•) Re-enrollment

Enrollment ID *

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 my hospital each time a new HCP affiliated with my hospital enrolls in the program. Note: You will automatically be notified of all HCPs 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)

Training & Enrollment Progress

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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 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

Training & Enrollment Progress

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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 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

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

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

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 my hospital each time a new HCP affiliated with my hospital enrolls in the program. Note: You will automatically be notified of all HCPs enrollment terminations, whether voluntary or for cause.

Click here if contact is the same as the authorized designee

Training & Enrollment Progress

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ESA APPRISE Oncology Program Enrollment For Hospitals

* indicates a required field.

Hospital Enrollment Information

Hospital Name *
Address *
City *
State *
ZIP Code *
HIN # *
- or -
DDD # *

☐ Search by ZIP code or City/State

Hospital Contact Information for Receipt of Program Materials

First Name *
Last Name *

☐ Same as hospital main address

Address *
City *
State *
ZIP Code *
Email Address *
Confirm Email Address *
Password *
Confirm Password *
Phone (###-###-####) *
Fax (###-###-####) *

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

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

Training & Enrollment Progress

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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

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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 and the hospital that has been enrolled.

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 HCP Program Starter Kit which contains the required materials for the ESA APPRISE Oncology Program for HCPs in your hospital.

HCP Program Starter Kit
Materials provided in the HCP Program Starter Kit include:

- ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms
- Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit ® (epoetin alfa) Medication Guides
- Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics

Until your starter kits arrive, download and print the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form. HCPs in your hospital must begin using this form with their patients.

For questions regarding the ESA APPRISE Oncology Program, please visit the ESA APPRISE Oncology Program Frequently Asked Questions page, 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 a reminder, patient registration or approval through the ESA APPRISE Oncology Program is not required.

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

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

Forms & Resources

Materials for Healthcare Providers

Order Program Materials

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

Enrollment ID:

Continue

Healthcare Provider and Hospital Designee Materials

- Dear Healthcare Provider (DHCP) Letter to HCPs who prescribe, or prescribe and dispense, ESAs for patients with cancer
- Dear Director of Pharmacy/Administrator Letter to hospitals that dispense ESAs for patients with cancer
- ESA REMS Flashcard
- ESA APPRISE Oncology Program Healthcare Provider Flashcard
- ESA APPRISE Oncology Program Hospital Process Overview Flashcard
- 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 Professional (HCP) Acknowledgment Form
- Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics NEW
- ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form - SPANISH

Prescribing Information

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

Materials for Patients

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: 3138387

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

Material Order : Address Selection

Personal Information

The Enrollment ID is associated to the following individual.

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

Practice Locations

Primary Practice Name *

Address *

City *

State *

ZIP Code *

☐ Select from the list of registered sites

Practice Contact Information

Confirm the following contact information is correct

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

☐ Primary contact is not listed

Next

Material Order : Address Selection

Personal Information

The Enrollment ID is associated to the following individual.

First Name John

Last Name Smith

Email Address john.smith@email.com

Practice Locations

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

Material Order : Address Selection

Personal Information

The Enrollment ID is associated to the following individual.

First Name John

Last Name Smith

Email Address john.smith@email.com

Practice Locations

Primary Practice Name *

Address *

City *

State *

ZIP Code *

☐ Select from the list of registered sites

Practice Contact Information

First Name *

Last Name *

Email Address *

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

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

☐ Select the registered primary contact

Next

Material Order : Specify Type and Quantity

Materials Selection

Select the materials you would like to order

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 Professional (HCP) Acknowledgment Forms
0	Tear-pad (25 sheets) ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms - SPANISH
Other Items	
0	Prepaid Reply Envelopes

Next

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 Professional (HCP) 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

Material Order : Your Current Order Items

Print this Page

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

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

Order Summary

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

Forms & Resources

Materials for Healthcare Providers

Order Program Materials

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

Enrollment ID:

Continue

Download Your Customized PAF

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

Enrollment ID

Cancel | Next >

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 Professional (HCP) Acknowledgment Form

Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics NEW

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

Prescribing Information

Aranesp® (darbepoetin alfa) full Prescribing Information

Epogen® (epoetin alfa) full Prescribing Information

Procrit® (epoetin alfa) full Prescribing Information

Materials for Patients

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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Get ADOBE® READER®

Forms & Resources

Materials for Healthcare Providers

Order Program Materials

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

Enrollment ID:

Continue

Download Your Customized PAF

Click the Practice Name to download the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) 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

ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form

Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics NEW

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

Prescribing Information

Aranesp® (darbepoetin alfa) full Prescribing Information

Epogen® (epoetin alfa) full Prescribing Information

Procrit® (epoetin alfa) full Prescribing Information

Materials for Patients

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

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

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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

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ESA APPRISE Oncology Program Login

Username

Password

Login

First time user? Forgot password? Click here.

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ESA APPRISE ONCOLOGY PROGRAM

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

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 Prescriber

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

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

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 Prescriber » Practice Location Management

Practice Location

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

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

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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

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

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

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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 Hospital Designee

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

Edit Profile
Keep your profile updated.

Change Password
Change your password.

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ESA APPRISE ONCOLOGY PROGRAM

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

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 Prescriber | Remove Prescriber

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 Hospital Designee » Hospital HCP Enrollment Management Report

Hospital HCP Enrollment Management Report

Affiliate Dashboard

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

Affiliated Prescriber Management

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

Enrollment ID

Cancel | Add Prescriber

Add Prescriber | Remove Prescriber

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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 Prescriber | Remove

Affiliated Prescriber Management

Do you really want to remove the following prescriber?

John Smith
Enrollment ID: 548789

By removing this prescriber, this individual will lose the ability to dispense and/or prescribe ESAs for patients with cancer from this location.

Cancel | Remove Prescriber

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 my hospital each time a new HCP affiliated with my 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 your 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

FAQs

Questions

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 all marketed erythropoiesis stimulating agents (ESA) [Aranesp®, Epogen® and Procrit®].

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Who must enroll in the ESA APPRISE Oncology Program?
All healthcare providers (HCPs), inclusive of licensed non-physicians, who prescribe or prescribe and dispense ESAs to treat cancer patients 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, e.g. pharmacy director or other Hospital Designee, must enroll in the ESA APPRISE Oncology Program.

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

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

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Why do I need to give out a Medication Guide if my practice has developed our own educational pieces?
The Medication Guide for the drug you are prescribing (Aranesp®, Epogen® or Procrit®) must be used as the review tool in counseling patients on the risks of that ESA. Your educational pieces can be given together with the Medication Guide, but cannot replace it.

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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 Professional (HCP) Acknowledgment Form.

To learn more about allowed changes to the Patient Acknowledgment Form, please refer to the Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics flashcard.

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Can the discussion with the patient on ESA risks and benefits be conducted by a nurse or other qualified health care professional?
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 health care professionals may still be involved in their standard patient education processes.

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

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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 was given the Medication Guide, had the risk:benefit discussion and signed the Patient Acknowledgment Form with the trained and enrolled prescriber of the ESA prior to receiving the injection.

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When I treat a patient with cancer in my private practice, do I need to send the signed patient acknowledgment form to the ESA APPRISE Oncology Program Call Center prior to administering the ESA?
No, the form can be sent after the ESA has been administered.

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Should I be concerned in sending my patient's name on the patient acknowledgment form to the ESA APPRISE Oncology Program Call Center?
No, by signing the patient acknowledgment form the patient has only authorized his/her name to be sent to the ESA APPRISE Oncology Program Call Center.

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Contact Us

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

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

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Please read this Privacy Policy carefully, as it will tell you:

- what information We collect about you and your use of Our Services
- how We collect, use, share, and protect that information
- the choices you have about how We use and share such information

By registering on Our Site or using our Services, you agree that you fully understand and consent to this Privacy Policy and to all other terms relevant to your use of Our Site or Services, including Our Terms of Use which are incorporated into this Privacy Policy by this reference.

This Site and its Services have been developed in response to the FDA's requirement of healthcare professionals to discuss with their patients the risks and benefits of treatment with Erythropoiesis Stimulating Agents (ESA) [Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa)]. In order to fulfill the requirement from the FDA to communicate the risk and benefits of these drugs to the healthcare professionals, Companies have created this Site and its Services to educate and certify that the healthcare professionals have conducted the appropriate training.

INFORMATION WE COLLECT

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As described below, you may choose to provide Us with Personal Information through Our Site or Services. "**Personal Information**" includes any information that could be used to identify or contact you such as your name, address, telephone number or e-mail address.

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User Accounts

In order to use certain Services, like chat rooms or message boards, you will be required to register and create a user account ("**User Account**"). You may be assigned or asked to choose a user name, login ID, or screen name (each a "**User Name**") and password. You will need to provide certain Personal Information such as your first and last name, address, telephone number, and e-mail address. You are responsible for maintaining and updating the registration information in your User Account with current and complete information.

We urge you to take steps to keep your registration information in your User Account safe by:

- memorizing your password or keeping it in a safe place (separate from your User Name), and
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Correspondence with Companies

You may contact Us at the ESA APPRISE CALL CENTER at 1-866-284-8089 to ask questions or report problems with this Site, Our Services or Our products.

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In some situations, We may collect Personal Information and other information about you through means other than this Site. For example, if you answer a poll or survey on a third party's web site (or through some other medium, such as by wireless phone), We may collect your information from the third party to fulfill some function in relation to your activity (e.g., to collect and analyze results) or if you request additional communications from Us. In addition, if you provide information to other companies who share information about their customers, We may collect information from those third parties about you. In each of these cases, We will apply this Privacy Policy to any Personal Information that is collected about you and combined with the information collected through this Site or Our Services.

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Information that is Routinely Collected By Our Site Technology

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HOW WE USE AND DISCLOSE YOUR INFORMATION

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Personal Information

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If you opt in to receive e-mail from Us by registering as a user of Our Site, you can always opt out of future messages by following the directions in each message to "unsubscribe" or by sending an e-mail to unsubscribe@esa-apprise.com. However, if you choose to opt out of future messages, We reserve the right to contact you regarding your account status, technical support, changes to account terms, and any other matter that might affect Our Site or Services.

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If you contact Us regarding your experience in using one of Our products, We may use the information you provide in submitting reports to the U.S. Federal Food and Drug Administration and as otherwise required of Us by law. We also may use and disclose the information you provide to contact the prescribing physician to follow up regarding an unexpected event involving use of Our product.

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We may contract with third parties to provide services for Our Site or Services. These contractors include vendors and suppliers who provide technology and content, vendors who analyze data collected on Our Site, and vendors who send or respond to e-mail on Our behalf (each a "Contractor"). These Contractors may have access to your Personal Information in order to provide services to Us or on Our behalf. If We allow a Contractor to have access to your Personal Information, We will not authorize the Contractor to use the information for any purpose that is not consistent with this Privacy Policy. We contractually prohibit Contractors from using Our cookies for their own purposes or placing their cookies on your computer when you access Our Site or Services.

Disclosure for Legal, Safety or Other Reasons

We may need to release Personal Information and other information associated with Personal Information to third parties:

- to respond to a request or complaint that you have made,
- to comply with legal or regulatory requirements, such as requests from the Food and Drug Administration, or
- in special cases in which We believe it is reasonably necessary to investigate, identify, or bring legal action against someone who may commit or cause harm, fraud, abuse, or illegal conduct.

We also reserve the right to cooperate with law enforcement authorities who investigate and prosecute those who engage in behavior that may be illegal or harmful anyone.

In the event that We are legally compelled to disclose your Personal Information to a third party outside of the purposes specified directly above, We will notify you, unless We believe that doing so would violate the law or a court order or pose a threat or danger to anyone.

Disclosure to Our Affiliates

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Except as set forth in this Privacy Policy or as you specifically agree or request, We will not disclose to any third parties any information We collect from or about you through Our Site or Services.

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If you ask Us or agree to share your Personal Information with a third party, your information will of course be subject to the third party's privacy policy, and you will need to contact the third party directly if you later decide that you do not want it to use your information.

California customers may request further information about our compliance with this law by contacting us at the ESA APPRISE CALL CENTER at 1-866-284-8089. Please note that we are only required to respond to one request per customer each year, and we are not required to respond to requests made by means other than through this toll-free telephone number.

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Correct, Update or Delete Personal Information

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All information that you provide via Our Services is stored in servers that are operated and maintained by Us or Our Contractors. You should be aware that it is not technologically practical to delete all information that We collect. The need to back-up Our systems to protect information from inadvertent loss means that a copy of information about you may exist in a non-erasable form that will be difficult or impossible for Us to locate. Nevertheless, upon receiving your request, We will delete all Personal Information stored in the databases We actively use for this Site. In addition, after receiving your request for removal, We will use commercially reasonable efforts not to disclose any Personal Information stored in a non-erasable form, except as required by law.

Finally, We reserve the right to maintain copies of information about you, including Personal Information, for as long as We deem it necessary for business purposes, subject to applicable law.

Communicate with Us by Telephone

You may communicate with Us via the ESA APPRISE CALL CENTER if you have questions about this Site or Our Services. We will not disclose Personal Information that We receive through the ESA APPRISE CALL CENTER unless such disclosure is necessary to respond to your request or inquiry or is otherwise permitted as described above.

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We will only use your Personal Information in the manner described in the Privacy Policy in effect when you provided the information. However, We will occasionally update this Privacy Policy. When We do, We will also revise the "effective date" set forth below. All updates to this Privacy Policy will be effective when posted, and your use of this Site or any of Our Services thereafter will constitute acceptance of those changes.

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Reference ID: 3138387

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If you have any questions about these Terms of Use, please call us at the ESA APPRISE Oncology Program Call Center: 1-866-284-8089.

Erythropoiesis Stimulating Agents (ESA) Risk Evaluation and Mitigation Strategy (REMS) Flashcard

For the use of Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa)

ESA REMS Requirements for Healthcare Providers (HCPs) and Hospitals

ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) **Oncology Program***	**ESA REMS Requirements for Healthcare Providers (HCPs) and Hospitals**	**ESA Other Indications**
✓	Dispense Medication Guide to patients to support informed decisions between the patient and his or her HCP	✓
✓	HCP certification via training and enrollment	
✓	Hospital certification via training and enrollment	
✓	Certified HCP and patient documentation of risk:benefit discussion	
✓	Confirmation of compliance with program requirements via site audits	
✓	Failure to enroll or re-enroll will result in suspension of access to ESAs	

*The ESA APPRISE Oncology Program is designed for oncology and hematology HCPs treating patients for their cancer.

Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa)/Procrit® (epoetin alfa) are different drugs with distinct dosing schedules.
Please see the Aranesp®, Epogen®, and Procrit® full prescribing information, including **Boxed WARNINGS**, and Medication Guides.
For more information, access the ESA APPRISE Oncology Program Website at **www.esa-apprise.com**, contact your local Amgen or Janssen Products, LP Field Representative, or call 1-866-284-8089.

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

ESA APPRISE Oncology Program
Enrollment Form for Healthcare Providers

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer*

To become certified, healthcare providers 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.

Check one: ❑ New enrollment ❑ Re-enrollment (required every 3 years)
Enter your enrollment ID #: ☐☐☐☐☐☐☐☐☐☐ (for re-enrollment only)

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 ESAs increased the risk of death from cardiovascular and thromboembolic reactions in clinical studies in patients with cancer treated with ESAs.
  - I understand that in order to decrease these risks, the lowest dose of ESAs should be used to avoid red blood cell 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 of treatment.
- 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®.

When I prescribe and dispense an ESA to a patient with cancer in my clinic, when an ESA is dispensed for administration under my supervision to a patient with cancer in an infusion center, or when I prescribe or order an ESA for a patient with cancer in a hospital:	I will provide an Aranesp® or Epogen®/Procrit® Medication Guide to each oncology patient at the initiation of each new course of the respective ESA therapy. After initiation of treatment, and for as long as treatment continues, I will provide the appropriate Aranesp® or Epogen®/Procrit® Medication Guide to each oncology patient once a month during regular office visits—or, if regular office visits occur less frequently than once a month, at the next regularly scheduled office visit.

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

- I will review the contents of the respective Medication Guide with the patient, counsel each patient on the risks (increased mortality, serious cardiovascular and thromboembolic reactions, and increased risk of tumor progression or recurrence) and benefits of Aranesp® or Epogen®/Procrit® I am prescribing to my patient before each new course of the respective ESA therapy. I will document that the discussion with each patient has occurred by signing the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form and by obtaining the patient's signature.
  - By signing the patient section of the form, the patient acknowledges the following:
    - I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:
      - I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
      - I have had all my questions or concerns about Aranesp® or Epogen®/Procrit® or my treatment answered by my healthcare professional.
      - I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots, and I may die sooner.
  - By signing the HCP section of the form, as a healthcare provider enrolled in the ESA APPRISE Oncology Program, I acknowledge that prior to prescribing my patient's first dose of Aranesp® or Epogen®/Procrit® therapy:
    - I provided my patient with the appropriate Aranesp® or Epogen®/Procrit® Medication Guide and instructed the patient to read it carefully before signing this form.
    - I counseled my patient on the risks and benefits of Aranesp® or Epogen®/Procrit®, using the respective Medication Guide as the review tool in counseling the patient.
    - I discussed all concerns and answered all questions my patient had about Aranesp® or Epogen®/Procrit® or his/her treatment to the best of my ability.
    - The patient signed the Acknowledgment Form in my presence.

When I 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 in an infusion center:	• I will send a signed copy of the ESA APPRISE Oncology Program Patient and Healthcare Professional Acknowledgment Form (or modified version consistent with the allowable changes) back to the ESA APPRISE Oncology Program Call Center and retain a copy for my records. • I agree that the ESA obtained for use in my patients with cancer will not be 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 ESA APPRISE Oncology Program Patient and Healthcare Professional Acknowledgment Form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

- I will comply with any program monitoring and 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 _____ E-mail _____

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 _____ E-mail _____

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 ______________ E-mail ______________

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 ______________ E-mail ______________

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 ______________ E-mail ______________

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 e-mail (or by fax if no e-mail address is provided) within 1 business day of receipt of this completed form. Within 5 business days of enrollment confirmation, an HCP Program Starter Kit including ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms and ESA Medication Guides will be shipped to each private practice location listed above. Your enrollment identification number will be required on every patient acknowledgment form.

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

*ESA=erythropoiesis stimulating agent (ESA; Aranesp®/Epogen®/Procrit®).
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

janssen

Steps for Healthcare Providers Who Prescribe or Prescribe and Dispense ESAs to 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 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 in patients with cancer.

2 Enroll

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

3 Inform

Prior to each new course of ESA therapy:

- Provide and review the appropriate Medication Guide and counsel each patient on the risks and benefits of ESAs. Review ESA risk:benefit information with your patient and answer any questions he/she may have.
- Document that the ESA risk:benefit discussion occurred using the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form. Fill in your ESA APPRISE Oncology Program enrollment ID number and ensure both you and your patient sign the form.
- If you are in a private-practice setting, send the form (or modified version consistent with the allowable changes) by facsimile to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124 or mail using the prepaid envelope to P.O. Box #29000, Phoenix, AZ 85038 and retain an archival copy of the form.
- If you are in a hospital setting, provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

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

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

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

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

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V3 05/12

ESA APPRISE ONCOLOGY PROGRAM

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

janssen

Aranesp® (darbepoe in alfa)

EPOGEN® (EPOETIN ALFA) RECOMBINANT

PROCRIT® EPOETIN ALFA

AMGEN Oncology

ESA APPRISE ONCOLOGY PROGRAM

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: 3138387

V3 05/12

ESA (erythropoiesis stimulating agent) APPRISE Training Module for Healthcare Providers

This 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 Training Module is the core requirement for enrollment within the ESA APPRISE Oncology Program, developed by Amgen and Janssen Products, LP. The ESA APPRISE Oncology Program is part of a Risk Evaluation and Mitigation Strategy (REMS). The Food and Drug Administration (FDA) has determined that a 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 shown in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

This training module is intended for HCPs who prescribe or prescribe and dispense ESAs for patients with cancer.

The goals of the REMS for Aranesp® and Epogen®/Procrit® are:

- To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Aranesp® or Epogen®/Procrit® by educating them on the risks of Aranesp® or Epogen®/Procrit®.
- For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE Oncology Program, is to mitigate the risk of shortened overall survival and/or increased risk of tumor progression or recurrence.

FAILURE TO ENROLL IN THE ESA APPRISE ONCOLOGY PROGRAM 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® to cancer patients.

The ESA APPRISE Oncology Program Training Module features four sections:

Section 1: Key safety information for the use of ESAs in 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.

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 schedules.
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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 IN 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 in Patients With Cancer

1. 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	Achieved Hemoglobin (Median Q1, Q3)	Primary Endpoint	Adverse Outcome for ESA-Containing Arm
Chemotherapy				
Cancer 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
Cancer Study 2 Lymphoid malignancy (n=344)	13–15 g/dL (M) 13–14 g/dL (F)	11.0 g/dL 9.8, 12.1 g/dL	Proportion of patients achieving a hemoglobin response	Decreased overall survival
Cancer 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 yr. relapse-free and overall survival
Cancer 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 yr. progression-free and overall survival and locoregional control
Radiotherapy Alone				
Cancer Study 5 Head and neck cancer (n=351)	≥15 g/dL (M) ≥14 g/dL (F)	Not available	Locoregional progression-free survival	Decreased 5 yr. locoregional progression-free survival Decreased overall survival
Cancer 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				
Cancer Study 7 Non-small cell lung cancer (n=70)	12–14 g/dL	Not available	Quality of life	Decreased overall survival
Cancer 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

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

2. ESAs increase the risk of serious cardiovascular and thromboembolic reactions.

An increased incidence of thromboembolic reactions, some serious and life-threatening, occurred in patients with cancer treated with ESAs. In a randomized, placebo-controlled study (Cancer Study 1) 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. Based on Kaplan-Meier estimates, at the time of study termination, the 12-month survival was lower in the epoetin alfa group than in the placebo group (70% vs. 76%; HR 1.37, 95% CI: 1.07, 1.75; $P = 0.012$).

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.

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

ESA APPRISE ONCOLOGY PROGRAM

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

Reference ID: 3138387

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Section 2
Appropriate Use of ESAs for Patients With Cancer

- ESAs are indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
- ESAs are not indicated for use:
  - in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
  - in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
  - as a substitute for RBC transfusions in patients who require immediate correction of anemia.
- ESAs have not been shown to improve quality of life, fatigue, or patient well-being.

Important Dosing and Treatment Information

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

Please see the 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.

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

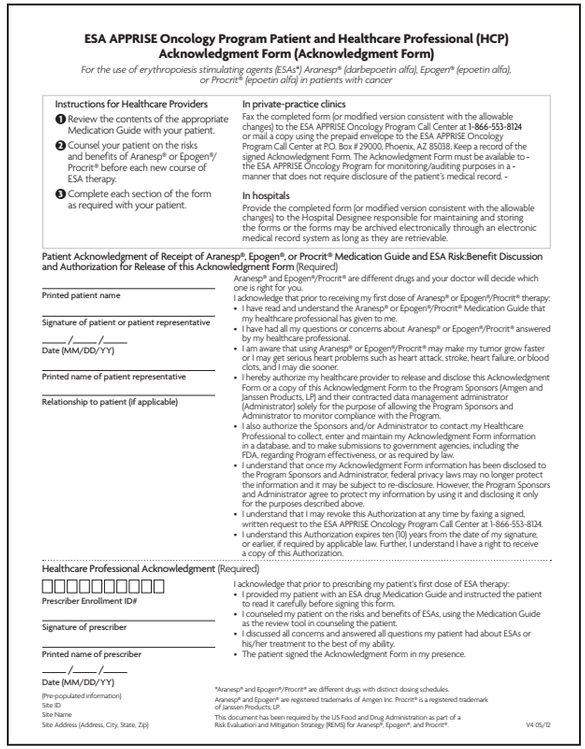
Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs

Section 3
Program Requirements and Materials for Healthcare Providers

HCP requirements for patient education and counseling

The ESA APPRISE Oncology Program requires HCPs to educate and counsel patients utilizing these program materials in the following manner:

- Provide the appropriate ESA Medication Guide to each patient prior to each new course of ESA therapy, review its contents, and counsel each patient on the risks and benefits of ESAs.
- Inform each patient that ESAs are associated with the following risks: increased mortality, serious cardiovascular and thromboembolic reactions, and increased risk of tumor progression or recurrence.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with the patient has occurred by completing and signing the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form.
- In a private practice-based setting, return the form (or modified version consistent with the allowable changes) via mail or fax (preferred method) to the ESA APPRISE Oncology Program Call Center as instructed on the acknowledgment form; maintain a copy of the signed ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form on-site.
- If you are in a hospital setting, provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.



ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form (Acknowledgment Form)

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer*

Instructions for Healthcare Providers

1. Review the contents of the appropriate Medication Guide with your patient.
2. Counsel your patient on the risks and benefits of Aranesp® or Epogen®/ Procrit® before each new course of ESA therapy.
3. Complete each section of the form as required with your patient.

In private-practice clinics

Fax the completed form (or modified version consistent with the allowable changes) to the ESA APPRISE Oncology Program Call Center at **1-866-553-8124** or mail a copy using the prepaid envelope to the ESA APPRISE Oncology Program Call Center at P.O. Box # 29000, Phoenix, AZ 85038. Keep a record of the signed Acknowledgment Form. The Acknowledgment Form must be available to the ESA APPRISE Oncology Program for monitoring/auditing purposes in a manner that does not require disclosure of the patient's medical record.

In hospitals

Provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

Patient Acknowledgment of Receipt of Aranesp®, Epogen®, or Procrit® Medication Guide and ESA Risk:Benefit Discussion and Authorization for Release of this Acknowledgment Form (Required)

Printed patient name

Signature of patient or patient representative

Date (MM/DD/YY) ___/___/___

Printed name of patient representative

Relationship to patient (if applicable)

Aranesp® and Epogen®/Procrit® are different drugs and your doctor will decide which one is right for you.

I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:

- I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
- I have had all my questions or concerns about Aranesp® or Epogen®/Procrit® answered by my healthcare professional.
- I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots, and I may die sooner.
- I hereby authorize my healthcare provider to release and disclose this Acknowledgment Form or a copy of this Acknowledgment Form to the Program Sponsors (Amgen and Janssen Products, LP) and their contracted data management administrator (Administrator) solely for the purpose of allowing the Program Sponsors and Administrator to monitor compliance with the Program.
- I also authorize the Sponsors and/or Administrator to contact my Healthcare Professional to collect, enter and maintain my Acknowledgment Form information in a database, and to make submissions to government agencies, including the FDA, regarding Program effectiveness, or as required by law.
- I understand that once my Acknowledgment Form information has been disclosed to the Program Sponsors and Administrator, federal privacy laws may no longer protect the information and it may be subject to re-disclosure. However, the Program Sponsors and Administrator agree to protect my information by using it and disclosing it only for the purposes described above.
- I understand that I may revoke this Authorization at any time by faxing a signed, written request to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124.
- I understand this Authorization expires ten (10) years from the date of my signature, or earlier, if required by applicable law. Further, I understand I have a right to receive a copy of this Authorization.

Healthcare Professional Acknowledgment (Required)

☐☐☐☐☐☐☐☐☐☐

Prescriber Enrollment ID#

Signature of prescriber

Printed name of prescriber

___/___/___

Date (MM/DD/YY)

I acknowledge that prior to prescribing my patient's first dose of ESA therapy:

- I provided my patient with an ESA drug Medication Guide and instructed the patient to read it carefully before signing this form.
- I counseled my patient on the risks and benefits of ESAs, using the Medication Guide as the review tool in counseling the patient.
- I discussed all concerns and answered all questions my patient had about ESAs or his/her treatment to the best of my ability.
- The patient signed the Acknowledgment Form in my presence.

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

*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®.

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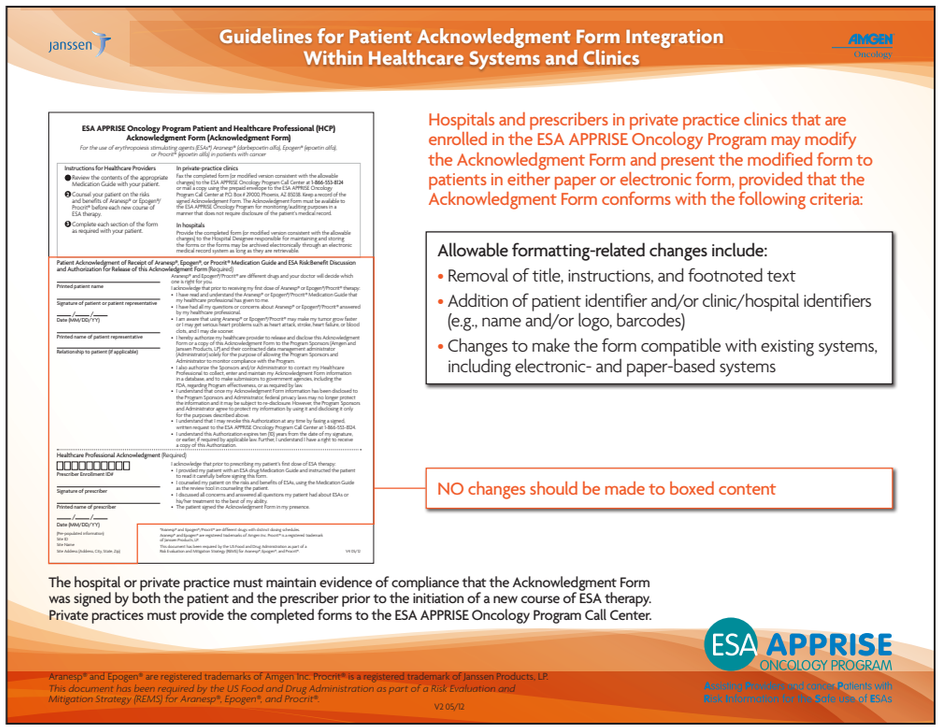
ESA APPRISE ONCOLOGY PROGRAM

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

Section 3
Program Requirements and Materials for Healthcare Providers

- To learn more about allowed changes to the Patient Acknowledgment Form, please refer to the Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics flashcard accessible at www.esa-apprise.com in the Forms and Resources section.



janssen

Guidelines for Patient Acknowledgment Form Integration Within Healthcare Systems and Clinics

AMGEN Oncology

ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form (Acknowledgment Form)

For the use of erythropoiesis stimulating agents (ESAs®) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer.

Instructions for Healthcare Providers

1 Review the contents of the appropriate Medication Guide with your patient.

2 Counsel your patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.

3 Complete each section of the form as required with your patient.

In private-practice clinics

Fax the completed form (or modified version consistent with the allowable changes) to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124 or mail a copy using the prepaid envelope to the ESA APPRISE Oncology Program Call Center at P.O. Box # 29000, Phoenix, AZ 85038. Keep a record of the signed Acknowledgment Form. The Acknowledgment Form must be available to the ESA APPRISE Oncology Program for monitoring/auditing purposes in a manner that does not require disclosure of the patient's medical record.

In hospitals

Provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

Patient Acknowledgment of Receipt of Aranesp®, Epogen®, or Procrit® Medication Guide and ESA Risk:Benefit Discussion and Authorization for Release of this Acknowledgment Form (Required)

Aranesp® and Epogen®/Procrit® are different drugs and your doctor will decide which one is right for you.

- I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:
- I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
- I have had all my questions or concerns about Aranesp® or Epogen®/Procrit® answered by my healthcare professional.
- I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots that can be fatal.
- I hereby authorize my healthcare provider to release and disclose this Acknowledgment Form or a copy of this Acknowledgment Form to the Program Sponsors (Amgen and Janssen Products, LP) and their contracted data management administrator (Administrator) solely for the purpose of allowing the Program Sponsors and Administrator to monitor compliance with the Program.
- I also authorize the Sponsors and/or Administrator to contact my Healthcare Professional and me for the purpose of collecting, using, and disclosing information in a database, and to make submissions to government agencies, including the FDA, regarding Program effectiveness, or as required by law.
- I understand that once my Acknowledgment Form information has been disclosed to the Program Sponsors and Administrator, federal privacy laws may no longer protect the information and it may be subject to re-disclosure. However, the Program Sponsors and Administrator agree to protect my information by using it and disclosing it only as described in this Authorization.
- I understand that I may revoke this Authorization at any time by faxing a signed, written request to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124.
- I understand this Authorization expires ten (10) years from the date of my signature, or earlier, if required by applicable law. Further, I understand I have a right to receive a copy of this Authorization.

Printed name patient

Signature of patient or patient representative

Date (MM/DD/YY)

Printed name of patient representative

Relationship to patient (if applicable)

Healthcare Professional Acknowledgment (Required)

Prescriber Enrollment ID#

- I acknowledge that prior to prescribing my patient's first dose of ESA therapy:
- I provided my patient with an ESA drug Medication Guide and instructed the patient to read it carefully before signing this form.
- I counseled my patient on the risks and benefits of ESAs, using the Medication Guide as the review tool in counseling the patient.
- I discussed all concerns and answered all questions my patient had about ESAs or his/her treatment to the best of my ability.
- The patient signed the Acknowledgment Form in my presence.

Signature of prescriber

Printed name of prescriber

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. 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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Hospitals and prescribers in private practice clinics that are enrolled in the ESA APPRISE Oncology Program may modify the 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 (e.g., 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 must maintain evidence of compliance that the Acknowledgment Form was signed by both the patient and the prescriber prior to the initiation of a new course of ESA therapy. Private practices must provide the completed forms to the ESA APPRISE Oncology Program Call Center.

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.
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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

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

A re-enrollment period will occur every 3 years for this program. You will be notified when re-enrollment is required.

Upon completion of this enrollment process you will receive an ESA APPRISE Oncology Program enrollment identification (ID) number via e-mail. Your enrollment ID number will be required on every patient acknowledgment form.

Once you have enrolled, you will receive the HCP Program Starter Kit to assist you in implementing the ESA APPRISE Oncology Program. The HCP Program Starter Kit will be shipped to each private practice location listed on your enrollment form.

Materials provided in the HCP Program Starter Kit:

- ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms
- Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa) Medication Guides
- Prepaid Reply Envelopes
- Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics

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

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

SECTION 4
HEALTHCARE PROVIDER ENROLLMENT

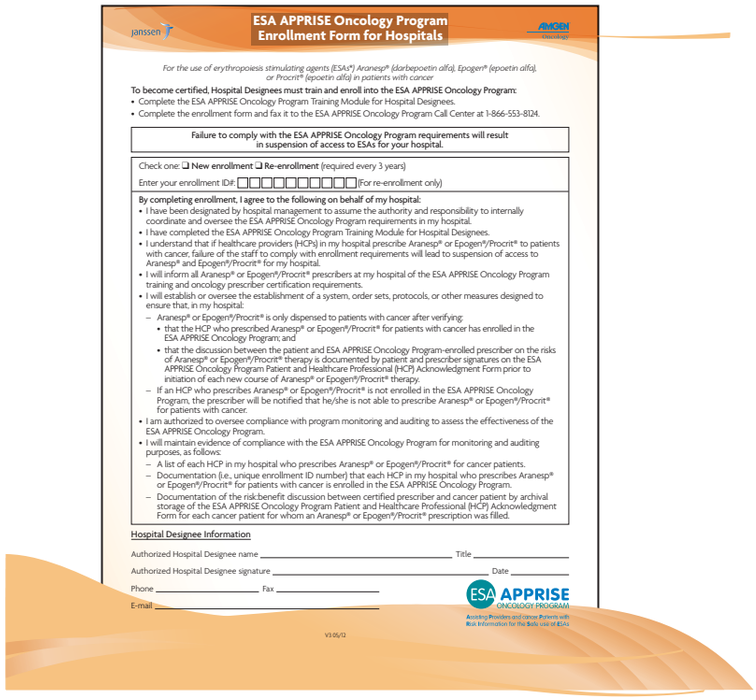
ESA APPRISE ONCOLOGY PROGRAM

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

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 in 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, including enrollment, will result in suspension of your access to ESAs.



ESA APPRISE Oncology Program Enrollment Form for Hospitals

For the use of erythropoiesis stimulating agents (ESAs®) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in 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 your hospital.

Check one: ❑ **New enrollment** ❑ **Re-enrollment** (required every 3 years)

Enter your enrollment ID#: ☐☐☐☐☐☐☐☐☐☐ (For re-enrollment only)

By completing enrollment, I agree to the following on behalf of my hospital:
- 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 my hospital.
- I have completed the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- I understand that if healthcare providers (HCPs) in my 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 my hospital.
- I will inform all Aranesp® or Epogen®/Procrit® prescribers at my hospital of the ESA APPRISE Oncology Program training and oncology prescriber certification requirements.
- I will establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that, in my hospital:
  - Aranesp® or Epogen®/Procrit® is only dispensed to patients with cancer after verifying:
    - that the HCP who prescribed Aranesp® or Epogen®/Procrit® for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
    - that the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) 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 enrolled in the ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
- I am authorized to oversee compliance with program monitoring and auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
- I will maintain evidence of compliance with the ESA APPRISE Oncology Program for monitoring and auditing purposes, as follows:
  - A list of each HCP in my hospital who prescribes Aranesp® or Epogen®/Procrit® for cancer patients.
  - Documentation (i.e., unique enrollment ID number) that each HCP in my hospital who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is enrolled in the ESA APPRISE Oncology Program.
  - Documentation of the risk-benefit discussion between certified prescriber and cancer patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form for each cancer patient for whom an Aranesp® or Epogen®/Procrit® prescription was filled.

Hospital Designee Information

Authorized Hospital Designee name _____ Title _____

Authorized Hospital Designee signature _____ Date _____

Phone _____ Fax _____

E-mail _____

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 schedules.

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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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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 to 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 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 in patients with cancer.

2 Enroll

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

3 Inform

Prior to each new course of ESA therapy:

- Provide and review the appropriate Medication Guide and counsel each patient on the risks and benefits of ESAs. Review ESA risk:benefit information with your patient and answer any questions he/she may have.
- Document that the ESA risk:benefit discussion occurred using the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form. Fill in your ESA APPRISE Oncology Program enrollment ID number and ensure both you and your patient sign the form.
- If you are in a private-practice setting, send the form (or modified version consistent with the allowable changes) by facsimile to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124 or mail using the prepaid envelope to P.O. Box #29000, Phoenix, AZ 85038 and retain an archival copy of the form.
- If you are in a hospital setting, provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

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

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

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V3 05/12

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 Professional (HCP) Acknowledgment Form (Acknowledgment Form)

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer*

Instructions for Healthcare Providers

1. Review the contents of the appropriate Medication Guide with your patient.
2. Counsel your patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
3. Complete each section of the form as required with your patient.

In private-practice clinics

Fax the completed form (or modified version consistent with the allowable changes) to the ESA APPRISE Oncology Program Call Center at **1-866-553-8124** or mail a copy using the prepaid envelope to the ESA APPRISE Oncology Program Call Center at P.O. Box # 29000, Phoenix, AZ 85038. Keep a record of the signed Acknowledgment Form. The Acknowledgment Form must be available to the ESA APPRISE Oncology Program for monitoring/auditing purposes in a manner that does not require disclosure of the patient's medical record.

In hospitals

Provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

Patient Acknowledgment of Receipt of Aranesp®, Epogen®, or Procrit® Medication Guide and ESA Risk:Benefit Discussion and Authorization for Release of this Acknowledgment Form (Required)

Printed patient name

Signature of patient or patient representative

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

Printed name of patient representative

Relationship to patient (if applicable)

Aranesp® and Epogen®/Procrit® are different drugs and your doctor will decide which one is right for you.

I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:

- I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
- I have had all my questions or concerns about Aranesp® or Epogen®/Procrit® answered by my healthcare professional.
- I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots, and I may die sooner.
- I hereby authorize my healthcare provider to release and disclose this Acknowledgment Form or a copy of this Acknowledgment Form to the Program Sponsors (Amgen and Janssen Products, LP) and their contracted data management administrator (Administrator) solely for the purpose of allowing the Program Sponsors and Administrator to monitor compliance with the Program.
- I also authorize the Sponsors and/or Administrator to contact my Healthcare Professional to collect, enter and maintain my Acknowledgment Form information in a database, and to make submissions to government agencies, including the FDA, regarding Program effectiveness, or as required by law.
- I understand that once my Acknowledgment Form information has been disclosed to the Program Sponsors and Administrator, federal privacy laws may no longer protect the information and it may be subject to re-disclosure. However, the Program Sponsors and Administrator agree to protect my information by using it and disclosing it only for the purposes described above.
- I understand that I may revoke this Authorization at any time by faxing a signed, written request to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124.
- I understand this Authorization expires ten (10) years from the date of my signature, or earlier, if required by applicable law. Further, I understand I have a right to receive a copy of this Authorization.

Healthcare Professional Acknowledgment (Required)

☐☐☐☐☐☐☐☐☐☐
Prescriber Enrollment ID#

Signature of prescriber

Printed name of prescriber

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

I acknowledge that prior to prescribing my patient's first dose of ESA therapy:

- I provided my patient with an ESA drug Medication Guide and instructed the patient to read it carefully before signing this form.
- I counseled my patient on the risks and benefits of ESAs, using the Medication Guide as the review tool in counseling the patient.
- I discussed all concerns and answered all questions my patient had about ESAs or his/her treatment to the best of my ability.
- The patient signed the Acknowledgment Form in my presence.

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

*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®.

janssen

AMGEN Oncology

ESA APPRISE ONCOLOGY PROGRAM

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

HCP Program Starter Kit

janssen

AMGEN Oncology

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer

Patient Education and Documentation Requirements for Healthcare Providers (HCPs)

Prior to each new course of ESA therapy:

- Provide and review the appropriate Medication Guide and counsel each patient on the risks and benefits of ESAs. Review ESA risk:benefit information with your patient and answer any questions he/she may have.
- Document that the ESA risk:benefit discussion occurred using the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form. Fill in your ESA APPRISE enrollment ID number and ensure both you and your patient sign the form.

If you are in a private-practice setting, send the form (or modified version consistent with the allowable changes) by facsimile to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124 or mail using the prepaid envelope to P.O. Box #29000, Phoenix, AZ 85038 and retain an archival copy of the form.

If you are in a hospital setting, provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

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ESA APPRISE ONCOLOGY PROGRAM

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

HCP Program Starter Kit Contents

- Aranesp® (darbepoetin alfa) Medication Guides
- Epogen® (epoetin alfa) Medication Guides
- Procrit® (epoetin alfa) Medication Guides
- ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms
- Prepaid Reply Envelopes
- Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics

To request additional HCP Program Starter Kits, contact your local Amgen or Janssen Products, LP Field Representative or call the ESA APPRISE Oncology Program Call Center at 1-866-284-8089.

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

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ESA APPRISE ONCOLOGY PROGRAM

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

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ESA APPRISE Oncology Program Enrollment Form for Hospitals

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in 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 your hospital.

Check one: ❑ **New enrollment** ❑ **Re-enrollment** (required every 3 years)

Enter your enrollment ID#: ☐☐☐☐☐☐☐☐☐☐ (For re-enrollment only)

By completing enrollment, I agree to the following on behalf of my hospital:

- 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 my hospital.
- I have completed the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- I understand that if healthcare providers (HCPs) in my 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 my hospital.
- I will inform all Aranesp® or Epogen®/Procrit® prescribers at my hospital of the ESA APPRISE Oncology Program training and oncology prescriber certification requirements.
- I will establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that, in my hospital:
  - Aranesp® or Epogen®/Procrit® is only dispensed to patients with cancer after verifying:
    - that the HCP who prescribed Aranesp® or Epogen®/Procrit® for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
    - that the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) 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 enrolled in the ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
- I am authorized to oversee compliance with program monitoring and auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
- I will maintain evidence of compliance with the ESA APPRISE Oncology Program for monitoring and auditing purposes, as follows:
  - A list of each HCP in my hospital who prescribes Aranesp® or Epogen®/Procrit® for cancer patients.
  - Documentation (i.e., unique enrollment ID number) that each HCP in my hospital who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is enrolled in the ESA APPRISE Oncology Program.
  - Documentation of the risk:benefit discussion between certified prescriber and cancer patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form for each cancer patient for whom an Aranesp® or Epogen®/Procrit® prescription was filled.

Hospital Designee Information

Authorized Hospital Designee name _____ Title _____

Authorized Hospital Designee signature _____ Date _____

Phone _____ Fax _____

E-mail _____

ESA APPRISE ONCOLOGY PROGRAM

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

Reference ID: 3138387

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 _____ E-mail _____

An ESA APPRISE Oncology Program enrollment confirmation and an identification number will be sent via e-mail (or by fax if no e-mail address is provided) to each individual listed above within 1 business day of receipt of this completed form. This confirmation e-mail will also include instructions on how to access a report of healthcare providers (HCPs) at your hospital who are enrolled in the program. Upon 5 business days of enrollment confirmation, an HCP Program Starter Kit including ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms and ESA Medication Guides will be shipped to the address provided above.

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

*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®.

ESA APPRISE ONCOLOGY PROGRAM

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

janssen

Aranesp® (darbepoe in alfa)

EPOGEN® (EPOETIN ALFA) RECOMBINANT

PROCRIT® EPOETIN ALFA

AMGEN Oncology

ESA APPRISE ONCOLOGY PROGRAM

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: 3138387

V3 05/12

ESA (erythropoiesis stimulating agent) APPRISE Training Module for Hospital Designees

This 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 Training Module is the core requirement for enrollment within the ESA APPRISE Oncology Program, developed by Amgen and Janssen Products, LP. The ESA APPRISE Oncology Program is part of a Risk Evaluation and Mitigation Strategy (REMS). The Food and Drug Administration (FDA) has determined that a 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 shown in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

This training module is intended for Hospital Designees at hospitals that dispense ESAs for patients with cancer.

The goals of the REMS for Aranesp® and Epogen®/Procrit® are:

- To support informed decisions between patients and their healthcare providers (HCPs) who are considering treatment with Aranesp® or Epogen®/Procrit® by educating them on the risks of Aranesp® or Epogen®/Procrit®.
- For treatment of patients with cancer, the goal of the REMS, as implemented through the ESA APPRISE Oncology Program, is to mitigate the risk of shortened overall survival and/or increased risk of tumor progression or recurrence.

FAILURE TO ENROLL IN THE ESA APPRISE ONCOLOGY PROGRAM WILL RESULT IN SUSPENSION OF YOUR 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® to cancer patients as well as the requirements for Hospital Designees who must oversee this safety program at their respective Hospitals.

The ESA APPRISE Oncology Program Training Module features four sections:

Section 1: Key safety information for the use of ESAs in 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® full prescribing information, including **Boxed WARNINGS**, and Medication Guides.

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

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 IN 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 in Patients With Cancer

1. 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	Achieved Hemoglobin (Median Q1, Q3)	Primary Endpoint	Adverse Outcome for ESA-Containing Arm
Chemotherapy				
Cancer 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
Cancer Study 2 Lymphoid malignancy (n=344)	13–15 g/dL (M) 13–14 g/dL (F)	11.0 g/dL 9.8, 12.1 g/dL	Proportion of patients achieving a hemoglobin response	Decreased overall survival
Cancer 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 yr. relapse-free and overall survival
Cancer 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 yr. progression-free and overall survival and locoregional control
Radiotherapy Alone				
Cancer Study 5 Head and neck cancer (n=351)	≥15 g/dL (M) ≥14 g/dL (F)	Not available	Locoregional progression-free survival	Decreased 5 yr. locoregional progression-free survival Decreased overall survival
Cancer 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				
Cancer Study 7 Non-small cell lung cancer (n=70)	12–14 g/dL	Not available	Quality of life	Decreased overall survival
Cancer 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

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 in Patients With Cancer

2. ESAs increase the risk of serious cardiovascular and thromboembolic reactions.

An increased incidence of thromboembolic reactions, some serious and life-threatening, occurred in patients with cancer treated with ESAs. In a randomized, placebo-controlled study (Cancer Study 1) 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. Based on Kaplan-Meier estimates, at the time of study termination, the 12-month survival was lower in the epoetin alfa group than in the placebo group (70% vs. 76%; HR 1.37, 95% CI: 1.07, 1.75; $P = 0.012$).

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.

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.

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.

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

Reference ID: 3138387

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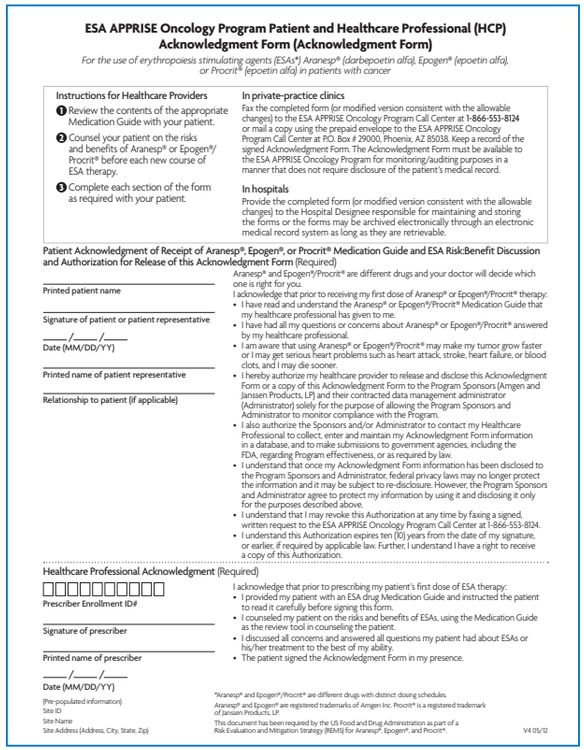
Section 3
Program Requirements and Materials for Healthcare Providers and Hospital Designees

HCP requirements for patient education and counseling

The ESA APPRISE Oncology Program requires HCPs to educate and counsel patients utilizing these program materials in the following manner:

- Provide the appropriate ESA Medication Guide to each patient prior to each new course of ESA therapy, review its contents, and counsel each patient on the risks and benefits of ESAs.
- Inform each patient that ESAs are associated with the following risks: increased mortality, serious cardiovascular and thromboembolic reactions, and increased risk of tumor progression or recurrence.
- Discuss each patient's questions or concerns about ESAs.
- Document that the risk:benefit discussion with the patient has occurred by completing and signing the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form.
- In a private practice-based setting, return the form (or modified version consistent with the allowable changes) via mail or fax (preferred method) to the ESA APPRISE Oncology Program Call Center as instructed on the acknowledgment form; maintain a copy of the signed ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form on-site.
- If you are in a hospital setting, provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.



ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form (Acknowledgment Form)

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer*

Instructions for Healthcare Providers

1. Review the contents of the appropriate Medication Guide with your patient.
2. Counsel your patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
3. Complete each section of the form as required with your patient.

In private-practice clinics

Fax the completed form (or modified version consistent with the allowable changes) to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124 or mail a copy using the prepaid envelope to the ESA APPRISE Oncology Program Call Center at P.O. Box # 29000, Phoenix, AZ 85038. Keep a record of the signed Acknowledgment Form. The Acknowledgment Form must be available to the ESA APPRISE Oncology Program for monitoring/auditing purposes in a manner that does not require disclosure of the patient's medical record.

In hospitals

Provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

Patient Acknowledgment of Receipt of Aranesp®, Epogen®, or Procrit® Medication Guide and ESA Risk:Benefit Discussion and Authorization for Release of this Acknowledgment Form (Required)

Printed patient name

Signature of patient or patient representative

____/____/____
Date (MM/DD/YY)

Printed name of patient representative

Relationship to patient (if applicable)

Aranesp® and Epogen®/Procrit® are different drugs and your doctor will decide which one is right for you.

I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:

- I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
- I have had all my questions or concerns about Aranesp® or Epogen®/Procrit® answered by my healthcare professional.
- I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots, and I may die sooner.
- I hereby authorize my healthcare provider to release and disclose this Acknowledgment Form or a copy of this Acknowledgment Form to the Program Sponsors (Amgen and Janssen Products, LP) and their contracted data management administrator (Administrator) solely for the purpose of allowing the Program Sponsors and Administrator to monitor compliance with the Program.
- I also authorize the Sponsors and/or Administrator to contact my Healthcare Professional to collect, enter and maintain my Acknowledgment Form information in a database, and to make submissions to government agencies, including the FDA, regarding Program effectiveness, or as required by law.
- I understand that once my Acknowledgment Form information has been disclosed to the Program Sponsors and Administrator, federal privacy laws may no longer protect the information and it may be subject to re-disclosure. However, the Program Sponsors and Administrator agree to protect my information by using it and disclosing it only for the purposes described above.
- I understand that I may revoke this Authorization at any time by faxing a signed, written request to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124.
- I understand this Authorization expires ten (10) years from the date of my signature, or earlier, if required by applicable law. Further, I understand I have a right to receive a copy of this Authorization.

Healthcare Professional Acknowledgment (Required)

☐☐☐☐☐☐☐☐☐☐
Prescriber Enrollment ID#

Signature of prescriber

Printed name of prescriber

____/____/____
Date (MM/DD/YY)

I acknowledge that prior to prescribing my patient's first dose of ESA therapy:

- I provided my patient with an ESA drug Medication Guide and instructed the patient to read it carefully before signing this form.
- I counseled my patient on the risks and benefits of ESAs, using the Medication Guide as the review tool in counseling the patient.
- I discussed all concerns and answered all questions my patient had about ESAs or his/her treatment to the best of my ability.
- The patient signed the Acknowledgment Form in my presence.

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

*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.

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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

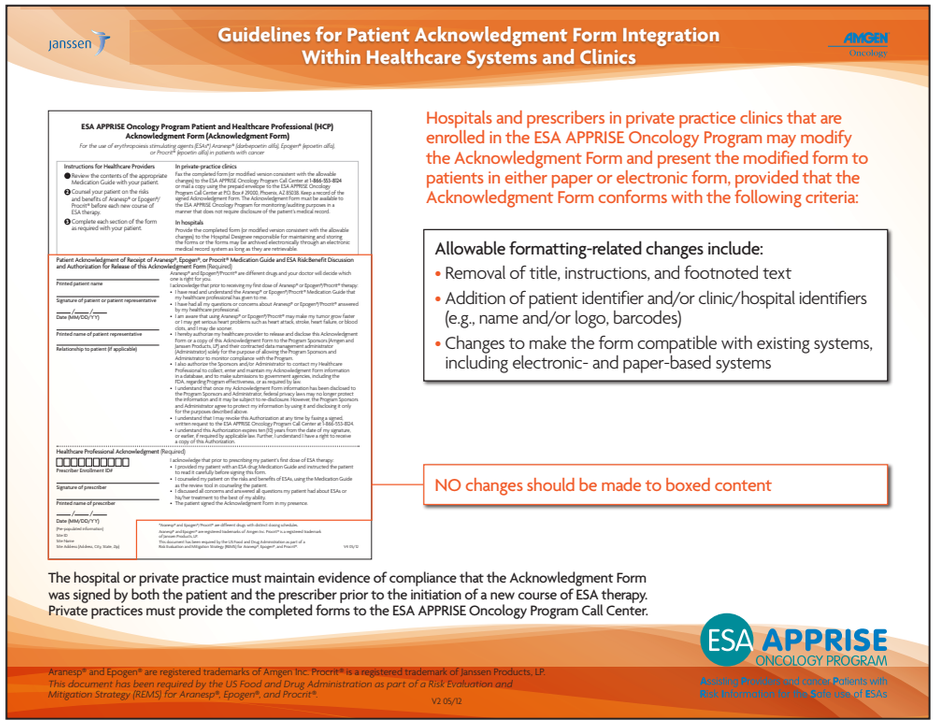
Hospital Designee Requirements

- Assume the authority and responsibility to internally coordinate and oversee the ESA APPRISE Oncology Program requirements in your hospital.
- Complete the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- Understand that if HCPs in your 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 ESAs for your hospital.
- Inform all Aranesp® or Epogen®/Procrit® prescribers at your hospital of the ESA APPRISE Oncology Program training and oncology prescriber certification requirements.
- Establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that, in your hospital:
  - ESAs are only dispensed to patients with cancer after verifying:
    - that the HCP who prescribed ESAs for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
    - that the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of ESA therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form prior to initiation of each new course of ESA therapy.
  - If an HCP who prescribes ESAs is not enrolled in the ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe ESAs for patients with cancer.

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

- To learn more about allowed changes to the Patient Acknowledgment Form, please refer to the Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics flashcard accessible at www.esa-apprise.com in the Forms and Resources section.



Janssen

Guidelines for Patient Acknowledgment Form Integration Within Healthcare Systems and Clinics

AMGEN Oncology

ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form (Acknowledgment Form)

For the use of erythropoiesis stimulating agents (ESAs®) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer

Instructions for Healthcare Providers

1. Review the contents of the appropriate Medication Guide with your patient.
2. Counsel your patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
3. Complete each section of the form as required with your patient.

In private-practice clinics

Fax the completed form (or modified version consistent with the allowable changes) to the ESA APPRISE Oncology Program Call Center at 1-866-353-8124 or mail a copy using the prepaid envelope to the ESA APPRISE Oncology Program, PO Box 1000, Cranbury, NJ 08512-1000. A copy of the signed Acknowledgment Form, the Acknowledgment Form must be available to the ESA APPRISE Oncology Program for monitoring/auditing purposes in a manner that does not require disclosure of the patient's medical record.

In hospitals

Provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

Patient Acknowledgment of Receipt of Aranesp®, Epogen®, or Procrit® Medication Guide and ESA Risk:Benefit Discussion and Authorization for Release of this Acknowledgment Form (Required)

Aranesp® and Epogen®/Procrit® are different drugs and your doctor will decide which one is right for you.

I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:

- I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
- I have had the opportunity to discuss concerns about Aranesp® or Epogen®/Procrit® answered by my healthcare professional.
- I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots, and I may die sooner.
- I hereby authorize my healthcare provider to release and disclose this Acknowledgment Form or a copy of this Acknowledgment Form to the Program Sponsors (Amgen and Janssen Products, LP) and the Program Administrator (Administrator) solely for the purpose of allowing the Program Sponsors and Administrator to monitor compliance with the Program.
- I also authorize the Sponsors and/or Administrator to contact my Healthcare Professional to collect, enter and maintain my Acknowledgment Form information in a database, and to make submissions to government agencies, including the FDA, regarding Program effectiveness, or as required by law.
- I understand that once my Acknowledgment Form information has been disclosed to the Program Sponsors and Administrator, federal privacy laws may no longer protect the information and it may be subject to re-disclosure. However, the Program Sponsors and Administrator agree to protect my information by using it and disclosing it only for the purposes described above.
- I understand that I may revoke this Authorization at any time by faxing a signed, written request to the ESA APPRISE Oncology Program Call Center at 1-866-353-8124.
- Unless revoked earlier, this Authorization expires ten (10) years from the date of my signature, or earlier, if required by applicable law. Further, I understand I have a right to receive a copy of this Authorization.

Printed patient name

Signature of patient or patient representative

Date (MM/DD/YY)

Printed name of patient representative

Relationship to patient (if applicable)

Healthcare Professional Acknowledgment (Required)

Prescriber Enrollment ID#

I acknowledge that prior to prescribing my patient's first dose of ESA therapy:

- I provided my patient with an ESA drug Medication Guide and instructed the patient to read it carefully before signing this form.
- I counseled my patient on the risks and benefits of ESAs, using the Medication Guide as a basis for discussion, before writing this order.
- I discussed all concerns and answered all questions my patient had about ESAs or his/her treatment to the best of my ability.
- The patient signed the Acknowledgment Form in my presence.

Signature of prescriber

Printed name of prescriber

Date (MM/DD/YY)

(Pre-populated information)

Work Name

Site Address (Address, City, State, Zip)

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NO changes should be made to boxed content

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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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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

- Oversee compliance with program monitoring and auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
- Maintain evidence of compliance with the ESA APPRISE Oncology Program for monitoring and auditing purposes, as follows:
  - A list of each HCP in your hospital who prescribes ESAs for cancer patients
  - Documentation (i.e., unique enrollment ID number) that each HCP in your hospital who prescribes ESAs for patients with cancer is enrolled in the ESA APPRISE Oncology Program
  - Documentation of the risk:benefit discussion between certified prescriber and cancer patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form for each cancer patient for whom an ESA prescription was filled

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.

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, including enrollment, will result in suspension of your hospital's access to ESAs.

A re-enrollment period will occur every 3 years for this program. You will be notified when re-enrollment is required.

Upon completion of this enrollment process, you (and an alternate contact, if provided) will receive an e-mail with the ESA APPRISE Oncology Program enrollment ID number unique to your hospital. This enrollment ID number allows you to identify HCPs enrolled at your location, by clicking the Hospital Designee log-in at the top right of the ESA APPRISE Oncology Program website home page. You can also order more ESA APPRISE Oncology Program materials via **www.esa-apprise.com** using the hospital enrollment ID number.

Once you have enrolled, you will receive the HCP Program Starter Kit to assist HCPs in your hospital in implementing the ESA APPRISE Oncology Program.

Materials provided in the HCP Program Starter Kit:

- ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Forms
- Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa) Medication Guides
- Guidelines for Patient Acknowledgment Form Integration within Healthcare Systems and Clinics

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

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

SECTION 4
HOSPITAL DESIGNEE ENROLLMENT

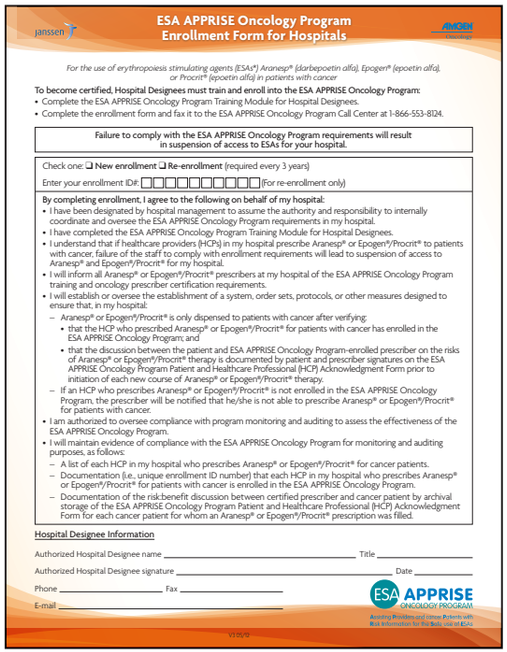
ESA APPRISE ONCOLOGY PROGRAM

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 in patients with cancer, and commits you to complying with the program requirements.

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



ESA APPRISE Oncology Program Enrollment Form for Hospitals

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in 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 your hospital.

Check one: ❑ **New enrollment** ❑ **Re-enrollment** (required every 3 years)

Enter your enrollment ID#: ☐☐☐☐☐☐☐☐☐☐ (For re-enrollment only)

By completing enrollment, I agree to the following on behalf of my hospital:
- 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 my hospital.
- I have completed the ESA APPRISE Oncology Program Training Module for Hospital Designees.
- I understand that if healthcare providers (HCPs) in my 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 my hospital.
- I will inform all Aranesp® or Epogen®/Procrit® prescribers at my hospital of the ESA APPRISE Oncology Program training and oncology prescriber certification requirements.
- I will establish or oversee the establishment of a system, order sets, protocols, or other measures designed to ensure that, in my hospital:
  - Aranesp® or Epogen®/Procrit® is only dispensed to patients with cancer after verifying:
    - that the HCP who prescribed Aranesp® or Epogen®/Procrit® for patients with cancer has enrolled in the ESA APPRISE Oncology Program; and
    - that the discussion between the patient and ESA APPRISE Oncology Program-enrolled prescriber on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) 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 enrolled in the ESA APPRISE Oncology Program, the prescriber will be notified that he/she is not able to prescribe Aranesp® or Epogen®/Procrit® for patients with cancer.
- I am authorized to oversee compliance with program monitoring and auditing to assess the effectiveness of the ESA APPRISE Oncology Program.
- I will maintain evidence of compliance with the ESA APPRISE Oncology Program for monitoring and auditing purposes, as follows:
  - A list of each HCP in my hospital who prescribes Aranesp® or Epogen®/Procrit® for cancer patients.
  - Documentation (i.e., unique enrollment ID number) that each HCP in my hospital who prescribes Aranesp® or Epogen®/Procrit® for patients with cancer is enrolled in the ESA APPRISE Oncology Program.
  - Documentation of the risk-benefit discussion between certified prescriber and cancer patient by archival storage of the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form for each cancer patient for whom an Aranesp® or Epogen®/Procrit® prescription was filled.

Hospital Designee Information

Authorized Hospital Designee name _____ Title _____

Authorized Hospital Designee signature _____ Date _____

Phone _____ Fax _____

E-mail _____

ESA APPRISE ONCOLOGY PROGRAM

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

V1 05/10

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ESA APPRISE ONCOLOGY PROGRAM

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V3 05/12

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 your hospital's access to ESAs [Aranesp® (darbepoetin alfa) and Epogen® (epoetin alfa)/Procrit® (epoetin alfa)].

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 (e.g., pharmacy director, Head of Hematology/Oncology Department).

2 Complete Training

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

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 prescribed Aranesp® or Epogen®/Procrit® for patients with cancer has enrolled in the ESA APPRISE Oncology Program.
  - If an HCP who prescribes Aranesp® or Epogen®/Procrit® is not enrolled in the ESA APPRISE Oncology Program, the prescriber 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-enrolled prescriber on the risks of Aranesp® or Epogen®/Procrit® therapy is documented by patient and prescriber signatures on the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form prior to initiation of each new course of Aranesp® or Epogen®/Procrit® therapy.

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

*ESA = erythropoiesis-stimulating agent (ESA; Aranesp®/Epogen®/Procrit®).

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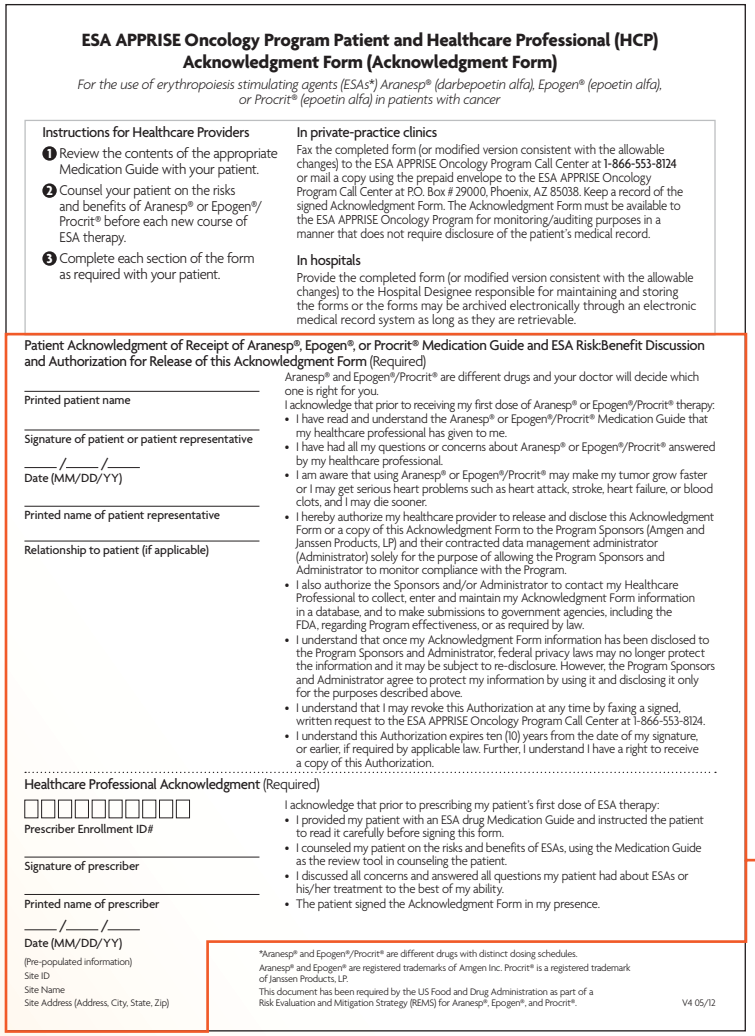
V3 05/12

ESA APPRISE ONCOLOGY PROGRAM

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

Guidelines for Patient Acknowledgment Form Integration Within Healthcare Systems and Clinics



ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgment Form (Acknowledgment Form)

For the use of erythropoiesis stimulating agents (ESAs) Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), or Procrit® (epoetin alfa) in patients with cancer*

Instructions for Healthcare Providers

1. Review the contents of the appropriate Medication Guide with your patient.
2. Counsel your patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
3. Complete each section of the form as required with your patient.

In private-practice clinics

Fax the completed form (or modified version consistent with the allowable changes) to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124 or mail a copy using the prepaid envelope to the ESA APPRISE Oncology Program Call Center at P.O. Box # 29000, Phoenix, AZ 85038. Keep a record of the signed Acknowledgment Form. The Acknowledgment Form must be available to the ESA APPRISE Oncology Program for monitoring/auditing purposes in a manner that does not require disclosure of the patient's medical record.

In hospitals

Provide the completed form (or modified version consistent with the allowable changes) to the Hospital Designee responsible for maintaining and storing the forms or the forms may be archived electronically through an electronic medical record system as long as they are retrievable.

Patient Acknowledgment of Receipt of Aranesp®, Epogen®, or Procrit® Medication Guide and ESA Risk:Benefit Discussion and Authorization for Release of this Acknowledgment Form (Required)

Printed patient name

Signature of patient or patient representative

____/____/____
Date (MM/DD/YY)

Printed name of patient representative

Relationship to patient (if applicable)

Aranesp® and Epogen®/Procrit® are different drugs and your doctor will decide which one is right for you.

I acknowledge that prior to receiving my first dose of Aranesp® or Epogen®/Procrit® therapy:

- I have read and understand the Aranesp® or Epogen®/Procrit® Medication Guide that my healthcare professional has given to me.
- I have had all my questions or concerns about Aranesp® or Epogen®/Procrit® answered by my healthcare professional.
- I am aware that using Aranesp® or Epogen®/Procrit® may make my tumor grow faster or I may get serious heart problems such as heart attack, stroke, heart failure, or blood clots, and I may die sooner.
- I hereby authorize my healthcare provider to release and disclose this Acknowledgment Form or a copy of this Acknowledgment Form to the Program Sponsors (Amgen and Janssen Products, LP) and their contracted data management administrator (Administrator) solely for the purpose of allowing the Program Sponsors and Administrator to monitor compliance with the Program.
- I also authorize the Sponsors and/or Administrator to contact my Healthcare Professional to collect, enter and maintain my Acknowledgment Form information in a database, and to make submissions to government agencies, including the FDA, regarding Program effectiveness, or as required by law.
- I understand that once my Acknowledgment Form information has been disclosed to the Program Sponsors and Administrator, federal privacy laws may no longer protect the information and it may be subject to re-disclosure. However, the Program Sponsors and Administrator agree to protect my information by using it and disclosing it only for the purposes described above.
- I understand that I may revoke this Authorization at any time by faxing a signed, written request to the ESA APPRISE Oncology Program Call Center at 1-866-553-8124.
- I understand this Authorization expires ten (10) years from the date of my signature, or earlier, if required by applicable law. Further, I understand I have a right to receive a copy of this Authorization.

Healthcare Professional Acknowledgment (Required)

☐☐☐☐☐☐☐☐☐☐
Prescriber Enrollment ID#

Signature of prescriber

Printed name of prescriber

____/____/____
Date (MM/DD/YY)

I acknowledge that prior to prescribing my patient's first dose of ESA therapy:

- I provided my patient with an ESA drug Medication Guide and instructed the patient to read it carefully before signing this form.
- I counseled my patient on the risks and benefits of ESAs, using the Medication Guide as the review tool in counseling the patient.
- I discussed all concerns and answered all questions my patient had about ESAs or his/her treatment to the best of my ability.
- The patient signed the Acknowledgment Form in my presence.

(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

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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/

JOSEPH E GOOTENBERG on behalf of PATRICIA KEEGAN
05/31/2012