janssen

AMGEN Oncology

Name
Address
City, State Zip

[Date]

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

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

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

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for ESAs to ensure that the benefits of these drugs outweigh the **risks of shortened overall survival and/or increased risk of tumor progression or recurrence**. As you may be aware, on 16 February 2010, the FDA approved a REMS for ESAs (Aranesp®, Epogen®/Procrit®) used to treat patients with cancer.

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

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

For oncology, ESAs are indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

For oncology, ESAs are not indicated for use:

- As a substitute for RBC transfusions in patients who require immediate correction of anemia.
- In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.

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

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

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

Sincerely,

Amgen
Janssen Products, LP

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

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

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

ESA APPRISE ONCOLOGY PROGRAM

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