Drug FAQs for Members
FREQUENTLY ASKED QUESTIONS

Safety Update:
Epogen (EPO), Procrit, and Aranesp Use in Cancer Patients

Names of medications: Epoetin alfa (sold as Procrit, Epogen), and Darbepoetin alfa (sold as Aranesp)

Background:

- The medicines listed above are erythropoiesis-stimulating agents or ESAs, for short. They are used to treat anemia, a condition where there is a lower than normal number of red blood cells in the blood. Red blood cells carry oxygen throughout the body and contain a protein known as hemoglobin. Blood tests which measure hemoglobin levels are used to evaluate a person's anemia and response to ESA therapy.
- ESAs have been commonly used in patients with cancer who are receiving chemotherapy. They help to increase the number of red blood cells, which may reduce or avoid the need for blood transfusions.
- In spite of these benefits, the U.S. Food and Drug Administration (FDA) has issued a series of alerts to healthcare professionals and to the public regarding growing concern about the risks of using ESAs, including its use in patients with cancer.
- Based on new information from recent studies, the package insert (doctor's prescribing information) now includes the following warning for the use of ESAs in patients with cancer:
  - Increased chance of death
  - Increased tumor (cancer) growth
  - Increased risk of heart attack, stroke and blood clots in the lungs, brain and major blood vessels

What is the latest news from the FDA?

- On January 3, 2008, the FDA announced results from two new studies which showed that patients with cancer who received an ESA died sooner or their tumors grew faster than patients who were not using an ESA.
  - The first was a large study, called the "PREPARE" study, in women with breast cancer who received chemotherapy before surgery and also received an ESA (Aranesp) to prevent anemia versus those who did not. After three years, it was found that more patients treated with Aranesp had died (14%) compared to those who did not receive this medication (9.8%). An additional finding was that tumor growth was faster in patients who received Aranesp versus those who did not.
  - Another large study, the "GOG-191", was sponsored by the National Cancer Institute's Gynecologic Oncology Group. It involved the use of an ESA (Procrit) in women with cervical cancer who were treated with chemotherapy and radiation. After three years, it was found that more patients who did not receive Procrit (66%) were alive and free of cancer growth compared to those who received the medication (58%). This study was stopped early due to life-threatening blood clots found in some of the patients who received Procrit.
- Findings from these two new studies build on what we have learned from previous studies add to the concern about ESA safety. There are now eight studies that show an increased chance of dying sooner or increased tumor growth in patients with cancer who used an ESA.

What are some of the most important facts I should know about ESAs?

- ESAs should only be used to treat anemia caused by chemotherapy to reduce the need for blood transfusions.
- ESAs should NOT be used to treat anemia in patients with cancer who are NOT receiving chemotherapy.
- ESAs are NOT proven to be effective in improving the symptoms of anemia, such as fatigue. Also, they have not been proven to improve the quality of life in patients with cancer.
- ESAs do NOT make cancer treatment more effective.
- If used, ESAs should be given at the lowest possible effective dose, with the goal of avoiding a blood transfusion.
- Once the chemotherapy course is completed, ESA treatment should be stopped.
- There is an increased risk of serious side effects, such as heart attack, stroke, blood clots in the lungs, brain and major blood vessels with use of ESAs.

Should I continue to use an ESA even with these safety concerns?

- If you are using an ESA, please discuss the new safety information with your health care provider before making any changes to your treatment.
- After discussing treatment options with your health care provider, if your final decision is to continue ESA therapy, make sure you keep your appointments for blood tests so your hemoglobin levels can be carefully watched.

What are my other treatment options for chemotherapy-related anemia?

- Red blood cell transfusion is another option for the treatment for anemia. Some patients may benefit from periodic blood transfusions. All treatment options carry some risk. You should talk with your health care provider about which treatment is right for you.
- Red blood cell transfusion corrects anemia faster than ESAs. It takes at least 2-6 weeks of ESA treatment before there is enough increase in the number of red blood cells to improve anemia.
- If you have any additional questions, please consult with your health care provider.