ERYTHROPOIESIS-STIMULATING AGENTS NOW TO BE PRESCRIBED UNDER REMS PROGRAM

This issue of New Drug FAX Sheet provides safety information regarding erythropoiesis-stimulating agents (ESAs). Studies have found these agents to be associated with tumor growth and decreased survival in cancer patients, and can increase cardiovascular risk in patients taking ESAs for other indications. The verbatim FDA drug safety communication has been provided below. If you need further information please contact the Samford University Global Drug Information Service at (205) 726-2659.

The FDA is requiring all drugs called Erythropoiesis-Stimulating Agents (ESAs) to be prescribed and used under a risk management program, known as a risk evaluation and mitigation strategy (REMS), to ensure the safe use of these drugs. The ESAs that are part of the REMS are marketed under the names Epogen, Procrit, and Aranesp. FDA required Amgen, the manufacturer of these products, to develop a risk management program because studies show that ESAs can increase the risk of tumor growth and shorten survival in patients with cancer who use these products. Studies also show that ESAs can increase the risk of heart attack, heart failure, stroke or blood clots in patients who use these drugs for other conditions.

ESAs work by stimulating the bone marrow to produce red blood cells. ESAs are approved for the treatment of anemia (low red blood cells) resulting from chronic kidney failure, chemotherapy, certain treatments for Human Immunodeficiency Virus (HIV), and also to reduce the number of blood transfusions during and after certain major surgeries.

As part of the REMS, a Medication Guide explaining the risks and benefits of ESAs must be provided to all patients receiving ESAs. In addition to the Medication Guide, Amgen was required to develop the ESA APPRISE (Assisting Providers and Cancer Patients with Risk Information for the Safe use of ESAs) Oncology program for healthcare professionals who prescribe ESAs to patients with cancer.

Under the ESA APPRISE Oncology program, Amgen will ensure that only those hospitals and healthcare professionals who have enrolled and completed training in the program will prescribe and dispense ESAs to patients with cancer. Amgen is also required to oversee and monitor the program to ensure that hospitals and healthcare professionals are fully compliant with all aspects of the program.

The goals of the REMS for the ESAs are:

- To support informed decisions between patients and their healthcare professionals who are considering treatment with an ESA by educating them on the risks of ESAs.
- To mitigate the risk of decreased survival and/or poorer tumor outcomes in patients with cancer by implementing the part of the REMS called the ESA APPRISE Oncology Program.

Additional information for patients and healthcare providers may be located on the FDA’s webpage (http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200297.htm).

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