Southern California
Renal Disease Council
INCORPORATED

ESRD NETWORK 18

M E M O R A N D U M

To: Clinic Manager

From: Shean Strong, QI Director
Lisle Mukai, QI Coordinator

Subject: **FDA: Drug Safety Communication – Erythropoiesis-Stimulating Agents (ESAs)**

Date: February 17, 2010

# FDA: Drug Saftety Communication
## *Erythropoiesis-Stimulating Agents (ESAs): Procrit, Epogen and Aranesp*

The Network is required to distribute information that can potentially affect ESRD facilities and/or patients. Attached please find more information regarding this communication and where to find the complete MedWatch 2010 Safety summary.

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.

As part of the REMS, a *Medication Guide* explaining the risks and benefits of ESAs must be provided to all patients receiving ESAs. The Medication Guides can be found on the FDA's website at **http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200297.htm#SA** under Related Information. 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.

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.

Please share this information as applicable within your organizations/practices. Thank you for your time and attention to this important patient safety issue.

*Cc: Steven Preston, Project Officer, CMS RO X*

## *Erythropoiesis-Stimulating Agents (ESAs): Procrit, Epogen and Aranesp: Drug Safety Communication*

FDA and Amgen notified healthcare professionals and patients that all ESAs must be used under a REMS risk management program. As part of the risk management program, a Medication Guide explaining the risks and benefits of ESAs must be provided to all patients receiving an ESA. 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. FDA is requiring a REMS 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.

**Patients with chronic kidney failure (includes patients on dialysis and those not on dialysis) using ESAs should:**

- Know that the use of ESAs can increase the risk for stroke, heart attack, heart failure, blood clots, and death.
- Read the ***Medication Guide*** to understand the benefits and risks of using an ESA.
- Get blood tests while using ESAs. The test results may help guide the course of therapy and lower the risks of using these drugs. Patients' healthcare professionals should make them aware of how often to have blood tests.
- Talk with their healthcare professional about any questions they have about the risks and benefits of using ESAs.

Read the complete MedWatch 2010 Safety summary including links to the Drug Safety Communication and current Prescribing Information for these products, at:
**http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm200391.htm**