



Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

July 25, 2011

This letter provides important new safety information regarding the new FDA modified recommendations for more conservative dosing of Erythropoiesis Stimulating Agents (ESAs) in patients with chronic kidney disease (CKD). More than 20 million people aged 20 years or older in the United States have CKD. Patients with CKD lose the ability to make red blood cells and become anemic. The ESAs treat certain types of anemia by stimulating the bone marrow to produce red blood cells and by decreasing the need for blood transfusions. Drugs in the ESA class are epoetin alfa (marketed as **Epogen** and **Procrit**) and darbepoetin alfa (marketed as **Aranesp**).

---Important Safety Information---

On 6/24/2011, the FDA released a new safety announcement detailing new recommendations regarding the dosing of ESAs in patients with CKD. The FDA has made these recommendations because increasing data has shown increased risks of cardiovascular events when used in this patient population. The key recommendations include:

- Using ESAs to target hemoglobin level of greater than 11 g/dL increases the risk of serious cardiovascular events (heart attack, heart failure, blood clots, and death) and has NOT been shown to provide additional benefit.
- Previous drug label included a hemoglobin target concept of 10-12 g/dL. This concept has now been removed from the current package labeling. The new recommendation is to use the lowest ESA dose sufficient to reduce the need for blood transfusion. If the hemoglobin approaches or exceeds 11 g/dL, reduce or interrupt the dose of ESA.
- When initiating or adjusting therapy, monitor hemoglobin levels at least weekly until stable, then monitor at least monthly

---Package Label Changes---

New Warnings/Precautions:

- In controlled trials with CKD patients, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target hemoglobin level of greater than 11 g/dL.
- No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.

303 E. Vanderbilt Way, San Bernardino, CA 92408

Tel (909) 890-2067 Fax (909) 890-2058

Visit our web site at: www.iehp.org

A Public Entity

New Dosing Recommendations:

- For patients with CKD, consider starting ESA treatment when the hemoglobin level is less than 10 g/dL. This advice does not define how far below 10 g/dL is appropriate for an individual to initiate. This advice also does not recommend that the goal is to achieve hemoglobin of 10 g/dL or hemoglobin above 10 g/dL. Individualize dosing and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions. Adjust dosing as appropriate.

More information can be found at: <http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm>

---IEHP Formulary Criteria---

The current IEHP criteria was developed and reviewed by the IEHP Pharmacy and Therapeutics Subcommittee.

ESA use in patients with CKD Criteria:

- For patients with chronic kidney disease (CKD) without dialysis:
 - Authorized for patients with hemoglobin level less than 10 g/dL
 - If hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of ESA and use the lowest dose to reduce the need for red blood cell transfusions
- For patients with chronic kidney disease (CKD) with dialysis
 - Authorized for patients with hemoglobin level less than 10 g/dL
 - If hemoglobin level exceeds 11 g/dL, reduce or interrupt the dose of ESA and use the lowest dose to reduce the need for red blood cell transfusions
- Pharmacy Exception Request for epoetin alfa in dialysis center is not required. The use of epoetin alfa must adhere to the criteria listed above. Recent hemoglobin level must be attached with the claims. Claims for epoetin alfa for patients who have hemoglobin level >12 g/dL will be denied

If you have any questions or comments regarding this change, please call IEHP Pharmaceutical Services Department at 909-890-2067.

Sincerely,

IEHP Pharmaceutical Services