

FDA Announces New Risk Management System for Use of Erythropoiesis-Stimulating Agents (ESAs) in People with Cancer

On Tuesday, February 16, 2010, the Food and Drug Administration (FDA) announced that it is creating a Risk Evaluation and Mitigation Strategy (REMS) for Erythropoiesis-Stimulating Agents (ESAs) (e.g., Procrit, Epogen, and Aranesp), which are used to treat anemia that can result from chemotherapy. While the most significant requirements of the ESA REMS apply to health care providers who **prescribe or dispense, but not those who only administer**, ESAs to patients with cancer, there are implications for oncology nursing practice. Many of the details have yet to be released, so the following is a summary of ONS's understanding to-date; we will provide regular updates to ONS members as the ESA REMS oncology program moves forward with implementation over the next 45 days.

Overview/FDA Rationale

The new program, which will be operated by Amgen, formally will be called the ESA APPRISE (Assisting Providers and Cancer Patients with Risk Information for the Safe Use of ESAs) Oncology program. The FDA website information states that the ESA APPRISE Oncology program is being created:

- “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.”

In explaining its rationale for requiring Amgen to create and operate the ESA APPRISE Oncology program, the FDA cites data that “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.” For more detail visit: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientandProviders/ucm200297.htm>

Requirements for Health Care Providers

The ESA APPRISE Oncology program, which is required to go into effect no later than 45 days from the February 16th 2010 announcement, will require:

- (1) Health care providers to disseminate to **all** (oncology and non-oncology) patients receiving an ESA for anemia the *Medication Guide* that explains the risks and

benefits of ESAs (dissemination of such patient *Medication Guides* has been occurring for some time – see links below for electronic versions of the guides);

- (2) Health care providers *who prescribe or dispense ESAs to patients with cancer* to (a) complete a training and receive certification through an on-line module operated by Amgen, and (b) register and maintain active enrollment in the ESA APPRISE Oncology program, with renewal/re-enrollment every three years (if a provider is not enrolled s/he will not be permitted to prescribe ESAs for patients with cancer); and
- (3) Health care providers *to counsel their cancer patients* with respect to the risks and benefits associated ESAs – this discussion must occur prior to the patient receiving an ESA and health care providers must secure, in advance of ESA treatment, a written confirmation from the patient that the discussion occurred (health care providers need to sign the form as well).

In addition, hospitals, separate and apart from individual health care providers, are required to:

- (1) Enroll in the ESA APPRISE Oncology program in order to dispense ESAs to patients with cancer (hospital enrollment is required even if the prescribing health care provider is separately certified under the program).
- (2) Implement a system to ensure that all health care providers, who prescribe ESAs to cancer patients in the hospital, are enrolled and in compliance with the ESA APPRISE Oncology program. (The FDA information does not distinguish between inpatient and outpatient hospital settings or providers.)

Healthcare professionals who only use ESAs for non-oncology patients are not required to enroll in the ESA APPRISE Oncology program; however, they are required to give their patients a copy of the *Medication Guide* when an ESA is dispensed.

Implications for Oncology Nursing Practice

FDA held a stakeholder call on February 16, 2010 during which an ONS representative specifically asked FDA staff for clarification of the definition of health care provider and asked about REMS requirements of oncology nurses vis-à-vis their role in the administration of ESAs. FDA staff clarified that the term health care provider under the REMS means an individual legally able to prescribe and dispense. As such, the REMS would include advanced practice nurses who prescribe ESAs; however, FDA staff specifically clarified that the REMS training, certification, and enrollment requirements **do not apply to individuals who administer, but do not prescribe, ESAs.**

ONS members who prescribe ESAs will have to participate in the REMS. While the REMS is only required of individuals who specifically **prescribe or dispense** ESAs, ONS notes that the new program likely will have practice implications for oncology nurses who work with patients who may be offered and/or treated with ESAs. There are a number of program details and compliance requirements that are not yet clear and ONS will be working with our oncology community colleagues to further evaluate the REMS and its implications for practice. In addition, if necessary, ONS will communicate with FDA and Amgen on any implementation concerns that may arise. As the new program becomes effective in 45 days, ONS encourages its members, as soon as possible, to discuss this new program, and its implications for oncology nurses and patient care, with their physician practice and hospital colleagues.

Resources

FDA Press Release February 16, 2010: FDA Announces New Safety Plan for Agents Used to Treat Chemotherapy-Related Anemia at

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm200471.htm>

Specific information and background on the ESA REMS under Drug Safety Communication: Erythropoiesis-Stimulating Agents (ESAs): Procrit, Epogen and Aranesp at

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientandProviders/ucm200297.htm>²

Aransep Patient Medication Guide

<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM085918.pdf>

Epogen Patient Medication Guide

<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM088591.pdf>

Procrit Patient Medication Guide

<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM088988.pdf>