APPRISE Oncology Program for Erythropoiesis-Stimulating Agents

By Karen Hagerty, MD

American Society of Clinical Oncology, Alexandria, VA

Background

On February 16, 2010, the US Food and Drug Administration (FDA) announced its approval of a new Risk Evaluation and Mitigation Strategy (REMS) for erythropoiesis-stimulating agents (ESAs). The ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program is part of the overall REMS and is oncology specific; the APPRISE program only applies to ESAs when they are prescribed for patients under FDA-approved cancer indications. At this time, the only element of the REMS that concerns prescribing ESAs in other settings is the requirement to dispense the medication guide.

Major elements of the REMS for oncology include:

- Physician educational module
- Physician enrollment
- Dispensation of medication guide to each patient at initiation of each course of therapy and monthly thereafter
- Physician review of medication guide with patient
- Physician assistance to patient in completing acknowledgment form
- Patient signature on acknowledgment form in presence of physician; physician also signs
- Copy of acknowledgment form is provided to manufacturer; original is filed in location separate from patient medical record
- Forms are maintained for auditing by manufacturer; manufacturer estimates amount of drug expected to be used by practice/physician based on number of forms filed and, for monitoring purposes, compares estimate with records of actual drug received
- Physician attests to understanding FDA-approved indications for ESAs.

There is no requirement that patients be enrolled in a centralized registry, although the manufacturer will receive copies of the acknowledgment forms of all patients receiving the drug. Enrollment in the APPRISE program began March 24, 2010. Providers have a grace period of up to 1 year, at which point they will no longer be eligible to prescribe ESAs without enrolling in the APPRISE program.

What Does This Mean for My Practice?

First, you need to decide whether you want to be able to continue prescribing ESAs. If so, you need to enroll in the APPRISE program. This involves either a visit to the APPRISE Web site or a telephone call to the manufacturer. You will

ASCO Response to the ESA REMS

ASCO has communicated the following concerns to its members:

- Program is unnecessarily burdensome
- No stakeholder input—from oncologists, patients, or interested members of the public—was solicited during REMS development
- REMS programs are inconsistent across different branches of FDA and among drugs.

review the educational materials and then sign forms attesting that you have completed the module and understand the FDA-approved indications. Next, you must consider the change in day-to-day office procedure. This program requires that the physician review the medication guide and acknowledgment form with the patient and personally observe the patient signing the form. Additional staff time will also be needed, because the form must be copied, the copy sent to the manufacturer, and the original filed in a location separate from the patient medical record. The process of reviewing the medication guide with the patient, obtaining signatures, and sending copies of the acknowledgment form to the manufacturer must occur at the initiation of therapy for every patient. If a patient stops ESA therapy and resumes at a later date, the whole process must be repeated. For patients on continuing therapy, a copy of the medication guide must be dispensed monthly. Finally, you will need to be prepared for audits by the manufacturer (or its designee). During these audits, a representative from the manufacturer will review the file of your original acknowledgment forms and assess whether you have received the amount of drug that might be expected, given the number of forms.

Conclusion

For each REMS, the manufacturer is required to submit to the FDA a timetable for assessment of the strategy, along with details of how such an assessment will be conducted. Generally, these assessments must at a minimum be submitted within 18 months and again within 3 years after the REMS is initially approved, with additional dates if more frequent assessments

Additional Resources

To learn more about the REMS for ESAs, visit <http://www.esa-apprise.com>. There you can view the educational module and patient forms and enroll in the program.

To view a complete list of FDA-approved REMSs, go to <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>.

are necessary to ensure that the benefits of the drug continue to outweigh the risks. Therefore, it is possible that this program will be amended over time. However, for oncologists wishing to

continue to prescribe ESAs in the current environment, enrollment in the APPRISE program will be necessary.

Accepted for publication on March 25, 2010.

Author's Disclosures of Potential Conflicts of Interest

The author indicated no potential conflicts of interest.

Corresponding author: Karen Hagerty, MD, American Society of Clinical Oncology, 2318 Mill Rd, Ste 800, Alexandria, VA 22314; e-mail: karen.hagerty@asco.org.

DOI: 10.1200/JOP.092002

The ASCO Cancer Foundation®

The ASCO Cancer Foundation is the philanthropic arm of the American Society of Clinical Oncology (ASCO). The ASCO Cancer Foundation is dedicated to improving the lives of people with cancer through programs that support cutting-edge research and education in oncology. The ASCO Cancer Foundation is the torchbearer for the next generation of oncology researchers and the purveyor of knowledge to cancer patients. With the support of the cancer community and the public at large, The ASCO Cancer Foundation is making a world of difference in cancer care.

For more information, visit www.ascocancerfoundation.org.

American Society of Clinical Oncology