

FDA Panel Votes in Favor of Increased Restrictions on Anemia Drugs

A U.S. Food and Drug Administration (FDA) advisory committee voted for new restrictions on anemia drugs, stemming from increased safety concerns around the products' use among anemic cancer patients and patients with chronic kidney disease (CKD). During its March 13, 2008, meeting, the Oncologic Drug Advisory Committee (ODAC) addressed safety concerns regarding the use of erythropoiesis-stimulating agents (ESAs) among anemic cancer patients. Numerous studies have linked the drugs to increased cardiovascular events among CKD patients and accelerated tumor growth and increased mortality rates among anemic cancer patients.

The committee voted 13-1 in favor of keeping the drugs on the market, noting that the studies have identified life-threatening conditions only when higher-than-recommended dosages were used. The committee addressed a need for additional studies aimed at patients being administered recommended dosages. In response, ESA manufacturers Amgen and Johnson and Johnson proposed a large scale study focused on patients receiving dosing consistent with the label, which, according to the representatives, will be available in five years.

The committee also issued recommendations regarding ESA use among specific cancer populations. In a 9-5 decision, the committee voted in favor of discontinuing use of ESAs among patients with breast cancer and head and neck cancer, explaining that the evidence of risk was most prevalent among these populations. Additionally, the committee voted in favor of discontinued use among patients being treated with intent to cure their cancers.

Although the latter population is vague and difficult to identify, cancer experts defined these patients as those with early stages of cancer who undergo surgery to remove the tumor, followed by chemo-

therapy treatments. Finally, the committee recommended that physicians require signed consent forms emphasizing that, before the drugs are prescribed, the treated patients should be informed about the risks associated with ESAs.

The meeting follows mounting controversy surrounding the safety of ESAs, marketed as Aranesp[®], Procrit[®], and Epogen[®]. While Epogen[®] is used mostly for patients with CKD undergoing dialysis, Aranesp[®] and Procrit[®] have been widely used among cancer patients. The meeting took place only weeks after the Journal of the American Medical Association (JAMA) published a meta-analysis of anemic cancer patients using ESAs, lead by Dr. Charles Bennett, which documented increased blood clots, tumor progression, and increased mortality rates among those treated with the drugs.

The FDA often follows its panelists' advice, although it is not required to do so. FDA officials said that they would consider the recommendations immediately but would not commit to a timetable for action.

For more information about the March 13 ODAC meeting, visit the FDA website at: www.fda.gov.

Did you know...

that Medicare is going to stop paying for hospital errors?

Effective October 1, 2008, Medicare will no longer pay for certain hospital errors, also dubbed "never events." In its FY 2008 Hospital Inpatient Prospective Payment System (IPPS) final rule, issued in August 2007, CMS states that it will no longer cover treatments resulting from incompatible blood transfusions, infections resulting from prolonged use of catheters in blood vessels, and second surgeries to retrieve objects left behind in bodies or treatment. Supporters state that the guidelines create an incentive to keep patients safe and will also save Medicare \$190 million over 5 years.



ESAs Accelerate Tumor Growth and Increase Mortality Rates

A new study published by the Journal of the American Medical Association links ESAs to increased episodes of blood clots, accelerated tumor growth, and increased mortality rates in anemic patients with cancer. Led by Charles Bennett, MD, of Northwestern University's Feinberg School of Medicine in Chicago, the study is significant because it is the first to provide quantitative evidence of increased mortality rates among cancer patients receiving ESAs and is based on the largest number of trials for this purpose to date. The meta-analysis, which examined 51 trials with more than 13,500 patients, revealed a 10 percent increase in mortality rates and a 57 percent increase in blood clots of the leg and lungs among cancer patients taking ESAs. Previous studies have identified increased blood clotting with ESAs. Investigators included phase 3 trials comparing ESAs with placebo or standard of care for the treatment of anemia among patients with cancer.

The ESAs erythropoietin and darbepoetin are the only FDA-approved treatments proven effective in producing red blood cells, providing an alternative

to blood transfusions for anemic cancer patients.

ESAs also are approved for anemia in patients with chronic kidney disease (CKD), in patients with HIV whose anemia is caused by AZT (zidovudine), and to reduce the number of transfusions after major surgery.

The study was published amid many controversies surrounding ESAs. In March 2007, the FDA issued a Public Health Advisory which warned of life-threatening risks associated with the drugs. The black box labeling warnings for all ESA products were updated in November 2007 and identified tumor growth and shortened survival in patients with advanced breast, head and neck, lymphoid, and non-small cell lung cancer when they received a dose that attempted to achieve a hemoglobin level of 12 grams per deciliter (g/dL) or greater. The warnings also clarified that no clinical data are available to determine whether there is a similar risk of shortened survival or increased tumor growth for patients with cancer who receive an ESA dose that attempts to achieve a hemoglobin level of less than 12 g/dL.

A Guide to Billing for Therapeutic Apheresis Procedures

Under Medicare, apheresis is defined as an autologous and continuous procedure, which is different from the procedure under which a patient donates blood preoperatively and is transfused with the donated blood at a later date. The site of service dictates which codes are necessary to bill to Medicare. In this issue, we provide coding guidelines for apheresis procedures performed in the hospital outpatient department (HOPD).

Therapeutic apheresis procedures are described by Current Procedural Technology (CPT) codes. Therapeutic apheresis has been split into several distinct services, CPT codes 36511-36516. When billing for procedures in the HOPD, providers use both the UB-04 and CMS-1500 billing forms. The UB-04 reports the facility's (in this case, the HOPD's) charges. Physicians bill separately for their professional charges on the CMS-1500. In both cases, providers should choose the CPT code that best describes the specific service being administered and report that CPT code on the claim forms. Additionally, providers should include the revenue code and the most appropriate ICD-9 diagnosis code or codes on the claim forms.

In the HOPD, payment for services is generally bundled according to the ambulatory payment classification (APC). Most services related to therapeutic apheresis are bundled under APC 0111 or 0112 (see table below). Payment will be based on the assigned APC.

Common Apheresis CPT Codes:

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| 36511 | Therapeutic apheresis; for white blood cells |
| 36512 | Therapeutic apheresis; for red blood cells |
| 36513 | Therapeutic apheresis; for platelets |
| 36514 | Therapeutic apheresis; for plasma pheresis |
| 36515 | Therapeutic apheresis; with extracorporeal immunoadsorption and plasma reinfusion |
| 36516 | Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion |

Common Apheresis APCs:

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|------|------------------------------------|
| 0111 | Blood Product Exchange |
| 0112 | Apheresis and Stem Cell Procedures |