

CONTENTS

Q&A: Anemia Drugs

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Q: Should I be concerned about the recent news regarding serious side effects resulting from chemotherapy-related anemia drugs?

A: During active cancer treatment, the primary use of erythropoietin drugs, or EPO—namely Procrit (epoetin alfa) and Aranesp (darbepoetin alfa)—is to increase red blood cells in anemic patients, resulting in fewer blood transfusions, less fatigue, and improved quality of life for some patients. More recently, oncologists use EPO drugs to raise red blood cell counts in patients who have chronic anemia related to their cancers, but who are not in active treatment.

The critical difference in these two situations is reason for concern. For patients receiving active chemotherapy, EPO drugs have proven benefit based on research studies. The other use—treating anemic cancer patients who are not on chemotherapy—has not been supported by similar extensive research. Their use in this circumstance is considered off-label, meaning the use is not firmly supported by scientific evidence.

Several studies recently called into question the value of these drugs in the off-label situation. Not only did the drugs not help these patients, some studies showed they resulted in increased harm, particularly blood clots, and decreased survival in certain groups. As a result, the Food and Drug Administration, in consultation with each drug's maker, determined a “black box” warning should be placed on the drugs' labels, signifying serious side effects, and doctors should be cautious when prescribing them.

Amgen and Johnson & Johnson agreed to halt their direct-to-consumer advertising until more is known after a request was made by a congressional committee in March. The FDA held a hearing in May to review data and recommended further restrictions on these drugs, including possible bans on use in certain patient populations.

Previously the most popular and most costly cancer-related supportive care drugs, 2006 sales for Aranesp reached \$4.1 billion plus \$3.2 billion for Procrit. Since doctors became aware of the problems, the use of EPO drugs in treating cancer-related anemia has decreased considerably.

Doctors still use EPO drugs to boost red blood cell counts in patients receiving chemotherapy, since the drugs are effective in this population. However, it's now recommended that the target blood count be lower with a goal of avoiding transfusions or severe anemia, not to get counts to a normal level. The excessive use of these drugs should not overshadow the real value they provide patients when used appropriately.

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