

# What to Know

## The ASCO and ASH Guideline on Epoetin and Darbepoetin Treatment for Adults With Cancer

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### KEY MESSAGES

- Epoetin and darbepoetin are drugs that may help treat anemia caused by chemotherapy, lowering the chances of needing a blood transfusion.
- These drugs have serious risks, including blood clots and an increased risk of death.
- It's important that both you and your doctor carefully consider the possible benefits and the risks before using epoetin or darbepoetin to treat chemotherapy-related anemia.

To help doctors give their patients the best possible care, the American Society of Clinical Oncology (ASCO) and the American Society of Hematology (ASH) developed evidence-based recommendations about the use of epoetin (Epogen, Procrit) or darbepoetin (Aranesp) for chemotherapy-related anemia. In 2010, this guideline was updated to reflect results of recent clinical studies and a new analysis of combined data on the use of these drugs. It also summarizes the changes to the U.S. Food and Drug Administration's (FDA's) approved prescribing recommendations. This guide for patients is based on the most recent ASCO and ASH recommendations.

### BACKGROUND

Anemia is a low level of red blood cells (also called low hematocrit), or of hemoglobin, which is the oxygen-carrying part of the red blood cell. When the levels of red blood cells and/or hemoglobin decrease, the body has to work harder to carry oxygen to the cells, which can cause fatigue, muscle weakness, and difficulty breathing. People are diagnosed with anemia using a simple blood test that shows decreased amounts of hemoglobin in the blood. Normal levels of hemoglobin are 12 to 18 grams per deciliter (g/dL), with men naturally having slightly higher levels than women.

Depending on the reason for the anemia, it may be treated in a variety of ways. Doctors generally try to find the cause of anemia and reverse it, such as stopping internal bleeding, if it is the cause. Other specific treatments, such as iron, folate, or vitamin B6 or B12 supplements, can reverse anemia caused by nutritional

deficiencies. Sometimes, while trying to find the cause, a red blood cell transfusion is used to replace blood for people who have symptoms or are very ill. Other times, epoetin or darbepoetin are used to increase blood cell production by the body.

Epoetin and darbepoetin are drugs that may help treat anemia caused by chemotherapy. They are similar to the hormone erythropoietin. Erythropoietin is made in the body naturally by the kidneys, and it helps the bone marrow produce more red blood cells in a process called erythropoiesis. For this reason, epoetin and darbepoetin are also called erythropoiesis-stimulating agents or ESAs. Epoetin and darbepoetin are given as a series of injections (shots) and can reduce the need for red blood cell transfusions and increase hemoglobin levels. However, these drugs also have risks, including the risk of serious or life-threatening blood clots. They have also increased the percentage of patients who died in some clinical studies. Furthermore, these drugs may increase tumor growth for some patients with cancer. In 2008, the FDA revised the drugs' labels to restrict the use of epoetin and darbepoetin to only those patients whose treatment is palliative (reducing the severity of symptoms to relieve a person's suffering); they should not be used for patients who are being treated in the hope of curing the cancer.

## RECOMMENDATIONS

The ASCO/ASH recommendations for epoetin and darbepoetin treatment are as follows:

- Epoetin and darbepoetin are equally effective for treating anemia from chemotherapy and have similar risks. These drugs should not be used if you are not receiving chemotherapy or if you are receiving chemotherapy to cure the cancer rather than as a palliative treatment. However, they may be considered if you have low-risk myelodysplastic syndrome (MDS), a disorder of the bone marrow that also may cause anemia, even when chemotherapy is not being given.
- If ESAs are being considered, your doctor should talk with you about the possible risks and benefits

of their use. They should be used only if you are receiving chemotherapy and have a hemoglobin level less than 10 g/dL. In addition, the risks and benefits should be compared with the risks and benefits of a red blood cell transfusion. ESAs should not be used unless your hemoglobin level falls below 10 g/dL.

- If used, ESAs should be given at the lowest dose needed to raise your hemoglobin levels just enough for you to avoid a blood transfusion, which may be different depending on your circumstances. The dose may be decreased when that level is reached, or if your hemoglobin level increases more than 1 g/dL within two weeks. If your hemoglobin levels aren't

## QUESTIONS TO ASK THE DOCTOR

To learn more about epoetin and darbepoetin treatment for chemotherapy-related anemia, consider asking your doctor the following questions:

- What is the cause of my anemia?
- How severe is my anemia?
- Am I receiving chemotherapy? What is the goal of my chemotherapy?
- Do I have a high risk of blood clots?
- Is epoetin or darbepoetin appropriate for my type of cancer?
- What are the possible risks of this treatment?
- How could these drugs affect my cancer?
- How will my treatment with epoetin or darbepoetin be monitored?
- How soon might I feel better if I am treated with epoetin or darbepoetin?
- Are there other ways to treat my anemia? What are my options?
- Will I need a blood transfusion if I don't get epoetin or darbepoetin?
- What are the possible risks of a blood transfusion?
- What is the chance that I may need a blood transfusion even if I am treated with epoetin or darbepoetin?
- What clinical trials are open to me?
- Where can I find more information?

rising after six to eight weeks, ESA treatment is not working and your doctor should stop ESA treatment.

- You and your doctor should be cautious about using these drugs if you have a high risk of developing blood clots. Risk factors include a previous blood clot, recent major surgery, long periods of bed rest or limited activity (such as being in the hospital), and certain types of chemotherapy and hormone therapy. Some types of treatment for multiple myeloma (especially thalidomide [Thalomid] or similar drugs) may also increase your risk of developing a blood clot. Learn more about preventing and treating blood clots at [www.cancer.net/whattoknow](http://www.cancer.net/whattoknow).

## WHAT THIS MEANS FOR PATIENTS

The use of epoetin and darbepoetin is one way to treat anemia caused by chemotherapy, when used according to the FDA-approved label. Treatment with one of these drugs can help patients avoid red blood cell transfusions, but it may also increase the risk of blood clots and death and may speed up tumor growth. There are other treatments that may be used for people with anemia who are receiving chemotherapy, and it is important for the doctor to rule out other causes of anemia and discuss the risks and benefits of each treatment option. Before starting treatment with epoetin or darbepoetin, your doctor should carefully discuss the risks and the benefits with you. After this conversation, you will be asked to sign a consent form indicating that you understand the risks of treatment. Be sure to talk with your doctor about any concerns you have about being treated with epoetin or darbepoetin, as well as about other ways to treat your anemia.

## HELPFUL LINKS

Read the entire clinical practice guideline at [www.asco.org/guidelines/esa](http://www.asco.org/guidelines/esa).

Managing Side Effects: Anemia  
[www.cancer.net/sideeffects](http://www.cancer.net/sideeffects)

American Society of Hematology  
[www.hematology.org](http://www.hematology.org)

## ABOUT ASCO'S GUIDELINES

To help doctors give their patients the best possible care, ASCO asks its medical experts to develop evidence-based recommendations for specific areas of cancer care, called clinical practice guidelines. Due to the rapid flow of scientific information in oncology, new evidence may have emerged since the time a guideline or assessment was submitted for publication. As a result, guidelines and guideline summaries, like this one, may not reflect the most recent evidence. Because the treatment options for every patient are different, guidelines are voluntary and are not meant to replace your physician's independent judgment. The decisions you and your doctor make will be based on your individual circumstances. These recommendations may not apply in the context of clinical trials.

The information in this patient guide is not intended as medical or legal advice, or as a substitute for consultation with a physician or other licensed health care provider. Patients with health care-related questions should call or see their physician or other health care provider promptly and should not disregard professional medical advice, or delay seeking it, because of information encountered in this guide. The mention of any product, service, or treatment in this guide should not be construed as an ASCO endorsement. ASCO is not responsible for any injury or damage to persons or property arising out of or related to any use of this patient guide, or to any errors or omissions.

## RESOURCES

The best cancer care starts with the best cancer information. Well-informed patients are their own best advocates, and invaluable partners for physicians. Cancer.Net ([www.cancer.net](http://www.cancer.net)) brings the expertise and resources of ASCO, the voice of the world's cancer physicians, to people living with cancer and those who care for and care about them. ASCO is composed of more than 28,000 oncologists globally who are the leaders in advancing cancer care. The information on Cancer.Net was developed and approved by the cancer doctors who are members of ASCO, making Cancer.Net an up-to-date and trusted resource for cancer

information on the Internet. Visit Cancer.Net to find guides on more than 120 types of cancer and cancer-related syndromes, clinical trials information, coping resources, information on managing side effects, medical illustrations, cancer information in Spanish, videos, podcasts, the latest cancer news, and much more. For more information about ASCO's patient information resources, call toll free 888-651-3038.

## ABOUT ASH

The American Society of Hematology (ASH) is the world's largest professional society concerned with the causes and treatments of blood disorders. The mission of the Society is to further the understanding, diagnosis, treatment, and prevention of disorders affecting the blood, bone marrow, and the immunologic, hemostatic and vascular systems, by promoting research, clinical care, education, training, and advocacy in hematology.



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