

**2007-2008 BOARD**

**PRESIDENT**

Nancy E. Davidson, MD

**IMMEDIATE PAST PRESIDENT**

Gabriel N. Hortobagyi, MD

**PRESIDENT-ELECT**

Richard L. Schilsky, MD

**TREASURER**

Bruce J. Roth, MD

**EXECUTIVE VICE PRESIDENT  
AND CHIEF EXECUTIVE OFFICER**

Allen S. Lichter, MD

**DIRECTORS**

Dean F. Bajorin, MD

Howard A. Burris, III, MD

Alexander M. Eggermont, MD, PhD

Waun Ki Hong, MD

Thomas A. Marsland, MD

Barbara L. McAneny, MD

Robert S. Miller, MD

Martin J. Piccart-Gebhart, MD, PhD

Kathleen I. Pritchard, MD

Gregory H. Reaman, MD

Deborah Schrag, MD, MPH

George W. Sledge, Jr., MD

Joel E. Tepper, MD

Jamie Hayden Von Roenn, MD

2008 Annual Meeting  
May 30-June 3, 2008  
Chicago, Illinois

For more information  
about ASCO Meetings  
Phone: (703) 631-6200  
Fax: (703) 818-6425  
Website: [www.asco.org](http://www.asco.org)

July 31, 2007

Louis B. Jacques, MD  
Director, Division of Items and Devices  
Coverage & Analysis Group, OCSQ  
Centers for Medicare & Medicaid Services  
Mailstop C1-09-06  
7500 Security Blvd  
Baltimore MD 21244

Re: Decision Memo for Erythropoiesis Stimulating Agents (ESAs) for non-renal disease indications (CAG-000383N)

Dear Dr. Jacques:

Thank you for discussing the CMS final decision memo for ESAs earlier today. As you know, the American Society of Clinical Oncology (ASCO) is the national organization representing physicians who specialize in the treatment of cancer. We have expressed to you a number of concerns about the decision, and this letter serves to reiterate and expand on those concerns.

**ESA Therapy Limited to Hemoglobin Below 10g/dL**

The new policy states that, for patients with anemia secondary to anticancer chemotherapy, ESAs are appropriate when the hemoglobin is less than 10. The new policy also restricts coverage of ESAs whenever a patient's hemoglobin goes above 10. This latter restriction is inconsistent with both the FDA-approved labeling and national guidelines. The FDA-approved label for Epogen states, "The dose of Epogen should be titrated for each patient to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for blood transfusion and not to exceed 12 g/dL." The FDA-approved label for Aranesp states, "For both dosing schedules, the dose should be adjusted for each patient to maintain the lowest hemoglobin level sufficient to avoid the need for RBC transfusion and not to exceed 12 g/dL." The ASCO/ASH guidelines recommend consideration of ESA therapy when the hemoglobin falls below 10 (for most patients), with a target hemoglobin of 12. The NCCN guidelines recommend titrating ESA dosage to maintain a hemoglobin of 11 to 12.

Under the new CMS policy, a patient's hemoglobin could repeatedly fall below 10 following termination of coverage at the end of 4-week periods. This consequence would be inconsistent with the FDA-approved labeling, which, as noted above, states that ESA dosing should be titrated to the individual patient to maintain the hemoglobin level. Under section 1861(t)(2) of the Social Security Act, Medicare is required to cover all FDA-approved uses of drugs and biologics used in chemotherapy regimens. The failure of the new policy to allow coverage of therapy designed to maintain an appropriate hemoglobin level is not consistent with the requirements of section 1861(t)(2). To be consistent with the labeling, we recommend that coverage be permitted as long as the dosage is being titrated to maintain a hemoglobin level less than 12.



### **Dose Escalation**

For hypo- or non-responders (patients with a rise in hemoglobin of less than 1 g/dL over 4 weeks of treatment), the new policy allows for a one-time dose escalation of 25%. Again, this is inconsistent with the FDA-approved label – and therefore the Medicare statute – and with national guidelines. The weight-based starting doses for darbepoetin and epoetin are, respectively, 2.25 mcg/kg (weekly) and 150 U/kg (three times a week). The FDA-approved labels state that, for hypo- or non-responders, weight-based dosing can be increased by 100% (i.e., up to 4.5 mcg/kg for darbepoetin, and to 300 U/kg for epoetin). The ASCO/ASH and NCCN guidelines offer similar recommendations.

### **Rate of Rise of Hemoglobin**

The new policy also states that if, “after any 2 week period of time,” hemoglobin rises by more than 1 g/dL, ESA treatment should be discontinued (if the hemoglobin is 10 or above) or the dose decreased (if the hemoglobin is less than 10). Our interpretation of this requirement is that patients will need to have weekly blood draws in order to assess the rate of hemoglobin rise over any given two week period (i.e., the rate of rise could exceed CMS’ threshold during weeks 1 to 3, 2 to 4, 3 to 5, etc.).

We strongly urge CMS to reconsider these restrictions in light of the concerns detailed above. These provisions in the decision will be difficult to implement, integrate into practice and may be an unnecessary inconvenience and expense for cancer patients.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, MD  
Chair, Government Relations Council