

August 8, 2007

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

Dear Dr. Phurrough:

The Association of Community Cancer Centers (ACCC) is writing to convey on continued concerns over the recent National Coverage Determination (NCD) on Erythropoiesis Stimulating Agents (ESAs) for non-renal disease indications (CAG-000383N). ACCC would like to request that CMS reopen the NCD process in order to better address the major concerns and issues we feel are still present at this time.

ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. We are concerned that the final NCD released on July 30, 2007 causes serious access problems for patients and creates many issues for physicians and hospitals alike. These issues include:

- Limiting usage of ESAs on patients with hemoglobin levels below 10 g/dL
- Limiting the discretion of physicians to lower or increase dosages
- Limiting the time that patients may be on ESA treatments
- Increasing the demand on the national blood supply
- Increasing the need for blood transfusions, which may lead to resource shortages at hospitals and leads to hardships for patients

ACCC addressed all of these issues in its original comments to CMS on June 4, 2007, and we are concerned that many of these issues remained in the final decision. In addition, ACCC conducted a survey of its member hospitals to measure the impact an increase in blood transfusions may have on their resources. A majority of respondents were concerned over this proposed NCD and ACCC shared these results with CMS prior to the release of the NCD.

ACCC shares the same concerns of other organizations when it comes to the topic of the clinical limitations on ESA usage. The American Society of Clinical Oncology (ASCO) and US Oncology have both submitted similar requests to CMS in the past week for a reopening and reconsideration of the NCD, In those letters to CMS, they both raise and detail these issues. ACCC supports both ASCO's and US Oncology's stance on these issues, and therefore will not repeat them again here.

In addition to the clinical aspects of the NCD, ACCC would ask that CMS look again at the survey results we submitted to CMS concerning the potential impact of increased blood transfusions on hospitals. With over 100 respondents, from a variety of hospital types and locations, we feel the results merit the attention of the coverage team at CMS. We would be happy to discuss the results further with CMS as they go forward with reconsidering this NCD.

ACCC feels that CMS should reopen the NCD, and also delay the changes until a final determination can be made. We agree with other advocacy groups that serious issues remain with the final NCD and we urge CMS to review the available clinical data and survey data in order to determine the true clinical aspect on patients and physicians, and the overall impact on the entire health care delivery system

Respectfully Submitted

A handwritten signature in black ink, appearing to read "Edward L. Braud". The signature is fluid and cursive, with a large initial "E" and a distinct "B" at the end.

Edward L. Braud, MD
Chair
Government Affairs Committee
Association of Community Cancer Centers (ACCC)