

May 31, 2007

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Steve Phurrough, M.D., MPA
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Baltimore, MD 21244

RE: Proposed Decision Memo for Erythropoiesis Stimulating Agents (ESAs) for non-renal disease indications (CAG-00383N)

Dear Dr. Phurrough:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed decision regarding the Medicare National Coverage Determination for Erythropoiesis Stimulating Agents (ESAs).¹ 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. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies that may improve patients' quality of life while they undergo treatments for this debilitating disease. Therefore, ACCC believes that CMS should not limit access to ESAs for proven FDA indications and compendia listings. Doing so may force them to undergo more lengthy blood transfusions, which may take them out of the community office setting, thus further detracting from their quality of life.

¹ <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=203>

ACCC does not agree with CMS' decision to enforce clinical limitations on ESA usage, both dosage and time limits, when that decision should be made by both the physicians and the Food and Drug Administration (FDA). When label indications are followed, ESAs can be very beneficial to patients, increasing their quality of life. The FDA has yet to determine what, if any, changes will be made to the label of ESAs after the recommendations of the Oncologic Drug Advisory Committee (ODAC) meeting of May 10, 2007. Because of this, the length of time and hemoglobin levels suggested in the proposal seems arbitrary and without an evidentiary basis.

In addition, we believe CMS has made an error in including anemia of Myelodysplastic Syndrome (MDS) in the non-covered category. MDS is a clonal myeloid disorder which may not evolve into acute leukemia, and it should not be included in this decision.

ACCC recognizes the desire of CMS to control costs in Medicare, which is presumably the reason why limitations on duration patients can be on ESAs was included in the proposal. However, it should be noted that taking a patient off of an ESA treatment in favor of blood transfusions or other treatments may be more costly than leaving patients on the medication.

ESAs can be effective as a maintenance tool, and do not only have to be used to raise hemoglobin levels. Often, ESAs are used to maintain a patients' hemoglobin level at the desired level, and may not raise it the required one gram that CMS has included as a stipulation for continuing treatment. ACCC feels that a better understanding of the disease state is necessary before these actions are taken. The most important aspect of using ESAs for treatment is not to over-rise a patient's hemoglobin level, while at the same time maintaining a level as close to normal as possible. Use of ESAs to accomplish this will thus limit the need for lengthy blood transfusions.

As a result of the proposal by CMS, more patients with MDS and chemotherapy induced anemia will require blood transfusions, which may take them out of the community setting where they are receiving chemotherapy. This will put a serious strain on the nation's blood supply, thus affecting not only cancer and MDS patients, but many other types of patients as well. It will also add an additional strain on hospital resources, with hospitals having to utilize more space and personnel to administer the transfusions.

ACCC feels that the best course of action for CMS to take would be to cover for all indications already on the FDA labels and to also use the guidelines for ESA usage that are already in place from the American Society of Hematology (ASH) and the American Society of Clinical Oncology (ASCO).

ACCC greatly appreciates this opportunity to comment on the proposed NCD. ACCC supports the proper usage of these drugs and the effects they can have on a patient's quality of life.

We would be pleased to answer any questions regarding these comments. Please contact Matthew Farber at 301-984-9496 ext. 221 if ACCC can be of any assistance as CMS continues to evaluate and develop its approach to coverage of ESAs.

Sincerely,

A handwritten signature in cursive script that reads "Richard B. Reiling".

Richard B. Reiling MD, FACS
President
Association of Community Cancer Centers (ACCC)