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April 11, 2007

BY ELECTRONIC FILING

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: NCA Tracking Sheet for Erythropoiesis Stimulating Agents
(ESAs) for Non-Renal Disease Indications (CAG-00383N)**

Dear Ms. Norwalk:

On behalf of the Association of Community Cancer Centers (ACCC), I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) NCA Tracking Sheet for Erythropoiesis Stimulating Agents (ESAs) for Non-Renal Disease Indications (CAG-00383N). 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 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent 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 in the most

appropriate settings. In addition, we believe it is vitally important for physicians to make clinical decisions based on what is best for their patients, not based on what can and can not be reimbursed.

ACCC is aware of the recent studies involving Erythropoiesis Stimulating Agents (ESAs) and appreciates CMS's concern for ensuring that these therapies are used appropriately by Medicare beneficiaries. If CMS decides to issue a new national coverage determination (NCD) for ESAs, we ask that the NCD be as clear as possible and continue to allow Medicare beneficiaries with cancer to receive ESAs for medically accepted indications, including those uses supported by the compendia or peer-reviewed medical literature.¹

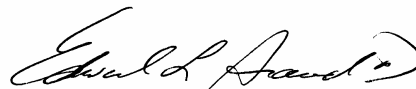
Several Medicare contractors and private payers have already announced that they will continue to cover ESAs when used for certain indications, including symptomatic anemia due to chemotherapy and anemia due to myelodysplastic syndrome. ACCC supports these actions and asks that CMS take them under consideration for the NCD.

In addition, the Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC) will hold a meeting on May 9-10, 2007, where data regarding the safe use of ESAs will be discussed. We ask that CMS hold off on any decisions until ODAC has completed its review of these data.

ACCC understands the need for CMS to clarify its coverage policies regarding ESAs in light of the recent studies. We ask that any further questions regarding coverage for ESAs that are not explicitly addressed in the NCD be left to the local carriers' discretion.

ACCC appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact Matt Farber at (301) 984-9496, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,



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

¹ See Social Security Act § 1861(t)(2)(B).