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April 9, 2007

Steve E. Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
Centers for Medicare & Medicaid Services  
Mail Stop C1-09-06  
7500 Security Boulevard  
Baltimore, MD 21244

RE: National Coverage Analysis for Erythropoiesis Stimulating Agents (ESAs) for  
Non-Renal Disease Indications (CAG-00383N)

Dear Dr. Phurrough:

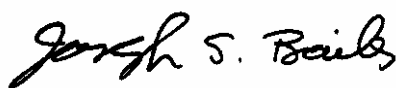
The American Society of Clinical Oncology (ASCO) appreciates the opportunity to provide comments on the initiation of a National Coverage Analysis (NCA) on administration of ESAs for non-renal disease applications. ASCO represents nearly 25,000 physicians and other health professionals who specialize in the treatment of cancer.

CMS has indicated its interest in receiving comments on clinical studies and other scientific information relevant to the use of ESAs in non-renal-disease applications. We understand that the Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) will be meeting in early May to review safety and efficacy data on ESAs. While we have reviewed the preliminary findings released by the FDA in March, ASCO would like the opportunity to analyze additional data that we expect to be presented at the ODAC meeting before providing substantive comments in the context of this NCA.

Based on our initial assessment, we believe that the off-label use of ESAs may be safe and effective in at least some conditions. As an example, the evidence-based clinical practice guideline developed jointly by ASCO and the American Society of Hematology on use of ESAs in cancer supports the use of epoetin for patients with anemia associated with low-risk myelodysplasia who are not receiving chemotherapy.<sup>1</sup> Pending completion of a comprehensive review, we urge that CMS and the Medicare contractors carefully analyze the use of ESAs in particular conditions and maintain access to these therapies where clinical data support their use.

Thank you for your consideration and we look forward to providing more detailed comments on this important issue soon.

Sincerely,



Joseph S. Bailes, MD  
Co-Chair, Government Relations Council

2007 Annual Meeting  
June 1-June 5, 2007  
Chicago, Illinois

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about ASCO Meetings  
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<sup>1</sup> Rizzo JD, Lichtin AE, Woolf SH, et al: Use of epoetin in patients with cancer: evidence-based clinical practice guidelines of the American Society of Clinical Oncology and the American Society of Hematology. *J Clin Oncol* 20:4083-107, 2002.