

Dear:

Thank you for your letter requesting a reconsideration of the recently posted Centers for Medicare & Medicaid Services' (CMS) final decision memorandum for the use of erythropoiesis-stimulating agents (ESAs) in cancer and related neoplastic conditions. We appreciate your interest in assuring that Medicare beneficiaries with cancer receive care that is safe, effective, and up-to-date with the current medical evidence.

The decision by CMS to open a National Coverage Analysis (NCA) was prompted by recently emerging safety concerns announced by the Food and Drug Administration (FDA). In light of these concerns, the FDA added "Black Boxed" warnings to labels for all ESA products marketed in the U.S. This action was based on analysis of recent research studies which found an increased risk of serious and life-threatening adverse events with the use of ESAs in cancer and non-cancer indications. The CMS NCA on the use of ESAs in cancer and related conditions resulted in the final decision memorandum that was published on July 30, 2007. The final NCD was based on an exhaustive review of more than 800 individual publications and approximately 2,600 comment letters received during the two public comment periods.

As outlined in a Federal Register notice in 2003 (September 26, 2003, vol 68, pp 55634-55638), CMS will reconsider an NCD when new evidence is presented or arguments are presented that the Agency materially misinterpreted existing evidence. In this case no new evidence was presented. To claim that the Agency materially misinterpreted the evidence in this NCD, it would be helpful to identify your specific concerns and the particular evidence that supports a different conclusion. For instance:

- What is the evidence that cancer patients undergoing chemotherapy require hemoglobin levels above 10 g/dL?
- What evidence demonstrates that cancer patients undergoing chemotherapy have better outcomes with hemoglobin levels above 10 g/dL? What is the evidence that ESA therapy is superior to transfusion therapy for maintaining that level?
- What is the evidence that using ESAs intermittently to maintain hemoglobin levels above 10 g/dL results in increased appropriate transfusions or higher adverse outcomes over the current practice of continuous use of ESAs?
- What is the evidence that cancer patients undergoing chemotherapy have better outcomes from ESA therapy vs. transfusions?
- What is the evidence that the higher dose of ESAs provided to most patients when using a fixed dose schedule rather than a weight based schedule does not results in higher adverse outcomes?

- What is the evidence that patients with comorbidities do better with a hemoglobin above 10 g/dL compared to those without comorbidities?

CMS is committed to supporting quality care that is safe for our beneficiaries. While we would, at any time, open an NCD for reconsideration based on the submission of information that meets one of the two criteria described previously, we want to insure that we have reviewed all the relevant information. To help facilitate this continued review, we are requesting that you consider these questions and provide the requested evidence within the next 30 days. We remain committed to an open and transparent process of evidence review to ensure that our beneficiaries receive high quality, safe care.

Sincerely,

Barry M. Straube, M.D.  
Chief Medical Officer  
Director, Office of Clinical Standards & Quality