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February 4, 2008

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Dear Acting Administrator Weems:

I am writing on behalf of the American Society of Clinical Oncology (ASCO) to express concerns regarding recently released CMS instructions implementing the July 30, 2007 National Coverage Decision "Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions." ASCO is the national organization representing physicians who specialize in the treatment of cancer, and Medicare coverage of ESAs is extremely important to our patients. Transmittal 1413, issued earlier this month, outlines contractor implementation instructions for the ESA National Coverage Decision (NCD). We are concerned that the Transmittal, as well as recent public statements by CMS officials, do not accurately reflect the NCD on use of ESAs and may therefore cause confusion for both physicians and contractors.

Our primary concern centers on language in the Transmittal which provides that claims for ESA use will be denied "when a hemoglobin 10.0g/dL or greater or hematocrit 30.0% or greater is reported." This instruction to the contractors is not consistent with the NCD.

Under the NCD, there is an initiation period that consists of the first four weeks of treatment. If the patient's hemoglobin or hematocrit is below the specified threshold at the beginning of that period, ESA use is covered for the entire four-week initiation period unless there is a rapid rise in the hemoglobin or hematocrit meeting specified criteria.

Specifically, the NCD states:

"Maintenance of ESA therapy is the starting dose if the Hb level remains below 10 g/dL (or hematocrit < 30%) 4 weeks after initiation of therapy."

"For patients with anemia secondary to anticancer chemotherapy, ESAs are appropriate when hemoglobin is <10 g/dL (hematocrit < 30%). If after the first 4 weeks the Hb is >10, ESAs are not covered....If after any 4-week ESA treatment cycle the Hb remains <10, ESAs may continue."

2008 Annual Meeting
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In addition, the CMS Questions and Answers document related to the NCD and published on July 31, 2007 included the following clarification regarding this issue:

“Q1. Will CMS reimburse or provide coverage for ESA treatment once a patient’s hemoglobin level exceeds 10 g/dL (or hematocrit exceeds 30%) regardless if it is their first dose or a “maintenance” dose?”

A1. The NCD covers the initial use of ESAs for a period of up to 4 weeks when the hemoglobin falls below 10 g/dL. After that period, additional claims for administration of ESAs is covered for the listed indications if a subsequent hemoglobin is <10 g/dL.”

Despite this guidance, contractors have in effect been instructed to deny claims at any time during the four-week period if the reported hemoglobin or hematocrit exceeds the value required for initiation of therapy. We would therefore like to request that the Transmittal and related policy guidance issued by the Agency be corrected as soon as possible to avoid further confusion.

We appreciate your consideration of this issue and would welcome the opportunity to discuss this with you further. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, slightly slanted style.

Joseph S. Bailes, MD
Chair, ASCO Government Relations Council

cc: Barry Straube, MD
Louis Jacques, MD