



May 21, 2007

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[CAGinquiries@cms.hhs.gov](mailto:CAGinquiries@cms.hhs.gov).

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

On behalf of the 400 members of the Florida Society of Clinical Oncology, I am writing to convey our comments and concerns regarding the Proposed Decision Memo for Erythropoiesis Stimulating Agents (ESAs) for Non-Renal Disease Indications (CAG-00383N).

We recognize that there are safety concerns regarding the use of ESAs. However, we feel that the proposed coverage decision inappropriately restricts use of ESAs because a number of the proposals are not supported by scientific data, rely on poor quality data, or are in conflict with expert scientific analysis. In particular, the proposed policy does not take into consideration recommendations made by FDA's Oncology Drug Advisory Committee during a May 10th meeting.

We are especially concerned about the exclusion of use of ESAs for treatment of anemia due to myelodysplasia (MDS). There is evidence to support the use of ESAs in a significant number of patients with anemia associated with MDS to decrease the need for blood transfusions. Unfortunately, there are few effective treatment options for MDS. Denial of coverage for ESAs will deprive patients with MDS of an effective therapy for their illness, one on which many of them already depend.

We are also dismayed by other aspects of the coverage decision which are arbitrary, premature, and not based on scientific data. These include the maximum covered treatment duration of 12 weeks per year, which is not adequate either for patients who are undergoing cancer chemotherapy or for those with anemia due to MDS. Likewise, the maximum four week dosage limits are inadequate, as is the limit of four weeks of treatment while awaiting response.

The State of Florida has a very large population of Medicare beneficiaries. Coverage decisions like this one affect a very significant portion of our patients. Our State Society 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. We believe that underuse of appropriate therapies is as detrimental as overuse. We feel that it is vitally important for coverage decisions like this one to be guided by the best available scientific evidence to ensure the highest degree of patient access and safety, and not to be based solely on economic considerations.

Sincerely,

Robert Cassell, MD, FLASCO President