

Congress of the United States
Washington, DC 20515

July 13, 2007

Ms. Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C5-11-24
Baltimore, Maryland 21244-1850

Mr. Herb Kuhn
Deputy Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C5-11-24
Baltimore, Maryland 21244-1850

Dear Ms. Norwalk and Mr. Kuhn,

We are writing to express our concern about a recently proposed National Coverage Decision (NCD) for erythropoiesis-stimulating agents for Medicare beneficiaries afflicted with cancer. As Members of the Cancer Care Working Group of the 110th Congress, and other Members of Congress dedicated to quality cancer care, we are committed to ensuring that all cancer patients have full access to physician determined treatments that are medically necessary in their battle against cancer.

The Centers for Medicare and Medicaid Services (CMS) recently issued a proposed NCD for erythropoiesis-stimulating agents (ESA's), treatments which can play an important role in helping beneficiaries cope with the debilitating side effects of chemotherapy treatments. Our concern is that the draft NCD could have a broad range of unintended public health consequences.

We understand that ESA's have been used safely in cancer patients for 20 years without a single reported clinical safety signal when used in accordance with clinical pathways that reflect mainstream practice. We are deeply concerned that limiting access to these therapies without abundant supporting clinical evidence will interfere with physicians exercising their best clinical judgments to serve the needs of individual patients, require a large population of Americans with cancer to manage their chemotherapy-related anemia through regular blood transfusions, and diminish both the quality of care and quality of life for Medicare beneficiaries with cancer.

Reduced access to ESA therapies could also adversely impact our national blood supply. According to the 2006 Nationwide Blood Collection and Utilization Survey, the number of transfusions of red blood cells in 2004 was nearly equivalent to the number of units collected, meaning there is virtually no margin of safety. Any increase in blood transfusions to cancer patients as a result of the proposed NCD is likely to cause blood shortages for patients with other afflictions, such as traumatic injuries. Conservative estimates of increased need of transfusions for anemic cancer patients denied ESA's are at a minimum 1.5 to 2 million units annually.

Even if the national blood supply were to grow to meet such a dramatic increase in need, the draft policy would require Medicare beneficiaries already afflicted with severe immunodeficiency to rely on transfusions, which are invasive procedures and carry a number of inherent risks for these already vulnerable patients. Additionally, for many patients this could require moving from the ambulatory treatment setting of a brief office visit to receive an ESA, to

a hospital visit for a minimum of 6-8 hours per transfusion. Besides the inconvenience to the patient, this could bring a corresponding rise in costs to the taxpayer and add to the already-strained hospital service systems.

The draft policy would disallow ESA's for patients using Herceptin and Avastin, even if the patient is receiving other toxic chemotherapy. This means breast cancer patients for whom Herceptin is frequently a lifesaving treatment would be required to undergo transfusions and endure their inherent risks, reasons for which the medical basis are unclear to us.

Finally, we are troubled by the potential of the proposed NCD to interfere with the ability of patients and physicians to make treatment decisions based on the best interests of the patient. Physicians and patients should be able to independently assess and balance the benefits and known risks of drug therapies when developing an individual's treatment plan.

We urge you to consider the public health consequences of this proposed decision. Inappropriately limiting ESA coverage could have dramatic and unintended implications for the quality of cancer care delivered to Medicare beneficiaries, transfusion rates, hospitalizations and other components critical to our health care delivery systems.

Thank you for your attention to our serious concerns. We look forward to your timely response.

Sincerely,

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Handwritten signature in blue ink, appearing to be Carolyn McCarthy

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