

June 14, 2007

Support Access to ESA Treatments for Patients with Cancer Related Anemia

Dear Colleague:

Please join us in signing the attached letter to the Centers for Medicare and Medicaid Services (CMS) regarding the proposed National Coverage Decision (NCD) for erythropoiesis-stimulating agents (ESA) for Medicare beneficiaries afflicted with cancer.

Anemia is a common complication for cancer patients that can cause symptoms including fatigue, dizziness, shortness of breath, palpitations, lack of endurance, and angina. ESA treatment helps alleviate the signs and symptoms of anemia, and help beneficiaries cope with the debilitating side effects of chemotherapy treatments. CMS recently issued a proposed NCD that could significantly reduce access to ESAs for cancer patients, and force cancer patients to rely on blood transfusions throughout their course of chemotherapy.

We are concerned that CMS' proposal will have a broad range of unintended public health consequences. Medicare beneficiaries would have to rely on transfusions that carry risks of transmissible diseases and iron toxicity. Transfusions would also require a hospital visit, with a minimum of six to eight hours for a transfusion, instead of a brief office visit to receive an ESA. Besides the inconvenience to the patient, the change in treatment could bring a corresponding rise in costs to the taxpayer and add to the already-strained hospital service systems. Reduced access to ESA therapies could also adversely impact the Nation's blood supply, as any increase in blood transfusions to cancer patients is likely to cause blood shortages for patients with other afflictions, such as traumatic injuries.

Please join us in expressing these concerns to CMS regarding its proposed NCD restricting beneficiaries' access to ESA. To sign the attached letter, please contact **Kelly Childress in Congressman Mike Rogers' office at 5-4872 or Tim Carey in Congresswoman Eshoo's office at 5-8890.**

Sincerely,



Anna Eshoo
Member of Congress



Mike Rogers
Member of Congress

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, 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 judgements 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 to rely on transfusions which carry risks of transmissible diseases and iron toxicity. 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.