

April 11, 2011

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Elizabeth A. Koller, M.D.  
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RE: Proposed Decision Memorandum for Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with CKD Including Patients on Dialysis and Patients not on Dialysis (CAG-00413N)

Dear Ms. Long and Dr. Koller,

Dialysis Patient Citizens (DPC) would like to thank the Centers for Medicare and Medicaid Services (CMS) for its recent decision not to issue a National Coverage Determination (NCD) for the use of erythropoiesis stimulating agents (ESAs) to manage anemia in patients who have chronic kidney disease (CKD). We believe this is a positive move for kidney patients because it places no extra barriers for patients and physicians to make decisions about the treatment of anemia. With over 22,000 members, DPC is America's largest dialysis patient organization. On a wide variety of issues we seek to ensure the patients' point of view is heard by decision makers.

Quality care requires a patient-centered approach, which the Institute of Medicine defines as "respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions." While we agree that science and clinical research should be used to promote and guide best practices that protect patients' health and safety, we also believe that physicians in consultation with their patients should have the autonomy to determine the most appropriate course of treatment. DPC believes that financial factors should not influence physicians' decisions to recommend the most optimal course of therapy. Physicians should discuss with their patients all the benefits and risk factors associated with using ESAs to treat anemia in kidney patients, as well as the risks of forgoing ESA therapy, so patients can make well-informed decisions. The decision to not issue an NCD falls very much in-line with our goal to ensure flexibility in the physician and patient decision making relationship.

While we agree with the decision by CMS to not issue an NCD at this time, we do have serious concerns with some of the assertions discussed in the proposed decision memo.

**Quality of Life**

When considering whether to regulate the use of ESAs for patients with CKD, it is important to take into consideration patients' self-reported quality of life. While we understand how patients feel or the quality of life they experience at different hemoglobin levels is difficult, if not impossible, to measure, this does not give reason to dismiss it. Avoidance of a blood transfusion, while important, is not the only issue patients experience with lower hemoglobin levels. Patients have attested to "feeling" changes in their hemoglobin, and when their hemoglobin is lowered, they experience greater fatigue, weakness and inability to think clearly, among other symptoms. Patients have reported this experience with even the slightest lowering of their hemoglobin. Any future decisions reached by CMS should fully consider patients' self-reported experiences.

**Consistency among Coverage Decisions and Quality Programs**

While we fully support the decision not to issue an NCD at this time, we urge CMS to ensure consistency throughout local coverage determinations (LCD) related to ESAs to make sure regional disparities are not made worse. Additionally, for dialysis patients the measurement of hemoglobin levels has been included in the end-stage renal disease (ESRD) Quality Incentive Program (QIP). In order for the QIP program to be effective LCDs will need to be in alignment.

**Transfusions and Transplantation**

Transplant centers have different requirements patients must meet in order to be considered for the kidney transplant waiting list; however, anemia management and the avoidance of transfusions is widely looked at as a determining factor. Patients know from experience that antibody levels in those who have received blood transfusions are scrutinized prior to a decision being made on whether or not the patient is a good match for a particular kidney transplant. Any changes to coverage and reimbursement of ESAs could impact a patient's anemia, their ability to get on the kidney transplant list and the length of time a patient lingers on the list.

In summary, DPC recommends CMS move forward with the proposal to not issue an NCD at this time for the use of ESAs in CKD patients. We also thank you for the opportunity to provide additional patient perspective on the use of ESAs to manage anemia in kidney patients.

Sincerely,



Nancy Scott  
Board President