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7/16/2010

Donald Berwick, M.D.

Administrator

Centers for Medicare & Medicaid Services

7500 Security Boulevard

Baltimore, Maryland 21244

RE: *NCA 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 Dr. Berwick:

National Patient Advocate Foundation (NPAF) is the voice for millions of patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained services from Patient Advocate Foundation (PAF), which provides professional case management assistance to patients with chronic, debilitating or life-threatening conditions. In 2009, PAF resolved 55,384 patient cases and received four million additional inquiries from patients nationally from all 50 states.

On behalf of those patients who encounter obstacles in accessing health care daily, we appreciate the opportunity to comment on the use of erythropoietin stimulating agents (ESAs) for the treatment of chronic kidney disease (CKD) and dialysis-related anemia in advance of the Centers for Medicare and Medicaid Services (CMS) proposed decision memorandum expected on March 16, 2011.

The alternative to the use of ESAs for anemia in patients on kidney dialysis and for those CKD patients not on dialysis is red blood cell (RBC) transfusion. RBC transfusion carries the risk of allo-sensitization which can reduce transplant eligibility and graft survival, transfusion reactions, potassium and iron overload, as well as HLA immunization.

ESAs, when administered in accordance with current clinical guidelines, can offer patients with anemia an improved quality of life. We recognize that there has been concern expressed that hemoglobin levels above 13 grams per deciliter may lead to adverse patient effects; and that the Food and Drug Administration has released a "Black Box" pronouncement that emphasizes potential risks facing dialysis patients who receive large doses of ESAs and have high hemoglobin. Hemoglobin levels are known to fluctuate in patients and factors such as the administration or non-administration of ESAs, pharmacokinetics, patient clinical status, and treatment protocols are suspect. We believe it is appropriate to characterize the current research as being incomplete relative to the optimal administration of ESAs for patients on dialysis and for those with CKD not on dialysis. Consequently, it would appear prudent to adhere to current guidelines that call for ESA use to maintain hemoglobin levels between 10 to 12 grams per deciliter until definitive scientific evidence causes a change in its use and administration.

The benefit that patients derive from properly administered ESAs may also be affected by CMS' effort to conform to Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) by replacing the current End Stage Renal Dialysis Disease (ESRD) basic case-mix adjusted composite payment system with a bundled ESRD prospective payment system for Medicare outpatient ESRD facilities beginning January 1, 2011. There is concern that bundling of ESAs in dialysis payments will disproportionately affect rural, not-for-profit centers and make dialysis less accessible to rural patients. If bundling, as conceived by CMS, adversely affects the appropriate use of ESAs, patient outcomes and quality of life may suffer. Hemoglobin levels will be lower, but there is a guard against under-utilization by making the floor 10 grams per deciliter in the pay-for-performance plan. The principle for maintaining access to ESAs for appropriate use for all patients, including by population status, must be upheld.

In its March 2010 Report to Congressional Requestors, END-STAGE RENAL DISEASE: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System (GAO-10-295), GAO notes that CMS recognizes the importance of monitoring the effect of its new bundled payment system on beneficiaries and is developing plans for these efforts. CMS plans to have a comprehensive monitoring strategy in place when the new bundled payment system is implemented on January 1, 2011. We urge CMS to acquire sufficient staff and resources to enable it to utilize its planned monitoring capability to assure that the totality of the quality of ESRD patient care does not suffer under this new payment system.

NPAF sincerely appreciates the opportunity to share its views on this matter. If we can be of assistance to CMS please do not hesitate to contact us.

Sincerely,



Nancy Davenport-Ennis
Chief Executive Officer

CC:

Dennis Gastineau, M.D.
Director, Human Cell Therapy Laboratory
Divisions of Transfusion Medicine & Hematology, Mayo Clinic

Steve Miller
Executive Vice President of Regulatory Affairs