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February 22, 2010

Charlene Frizzera

Acting Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attn: CMS-3222-N

7500 Security Boulevard

Baltimore, MD 21244-1850

Re: Erythropoiesis-Stimulating Agents in Anemia Related to Kidney Disease (CMS-3222-N)

Dear Administrator Frizzera:

On behalf of the patients served by Patient Advocate Foundation, National Patient Advocate Foundation is pleased to submit comments to MedCAC regarding Erythropoiesis-Stimulating Agents (ESA's) in Anemia Related to Kidney Disease. National Patient Advocate Foundation's Scientific Advisory Committee of the Board of Directors chaired by Dr. Robert Rifkin, MD, FACP, Director of NMDP Collections at Rocky Mountain Cancer Centers and Scientific Advisor to the Executive Board of Directors, Dr. Dennis Gastineau, MD, Chair, Division of Hematology at the Mayo Clinic, are in support of the positions taken by the American Society of Clinical Oncology (ASCO).

National Patient Advocate Foundation supports the following positions taken by ASCO in response to the ESA REMS on February 20, 2010:

“While ASCO supports efforts to raise risk awareness and promote patient safety, we strenuously object to duplicative requirements that further diminish time and resources available for patient care.”[1]

“ASCO has noted with growing concern the process by which REMS are imposed without input from the physician community.”[1]

“ASCO and its members were not part of the development of this latest REMS, and yet the resulting system will have a significant impact on the day-to-day practice of hematology and oncology.”[1]

“When oncologists will be asked to employ a REMS in the clinic, ASCO feels strongly that our members should be represented during the development or review process.”[1]

In addition, patients with chronic kidney disease are also placed at great risk, including cardiovascular and cerebrovascular events and death, when prescribed ESAs. For example, patients on hemodialysis receiving erythropoietin exhibited a higher mortality rate and incidence of myocardial infarction when the target was a normal hemoglobin. [2] Another study also demonstrated increased mortality for chronic kidney disease patients not on hemodialysis who received erythropoietin with a higher versus lower hemoglobin target, [3] with greater risk for a higher hemoglobin target for those patients who did not have concomitant heart failure or diabetes mellitus. [4]

Moreover, there is nearly a two-fold risk of stroke for renal failure patients on darbepoetin compared to those on placebo, with an increase in cardiovascular events and mortality as well, [5] comparable to the increased risk of mortality for cancer patients. Therefore, all prescribing physicians whose patients could be exposed to ESA's should follow uniform programs and guidelines.

Thank you for the opportunity to submit comments on CMS-3222-N. If we can be of assistance, please do not hesitate to contact me.

Sincerely,



Nancy Davenport-Ennis
Chief Executive Officer

[1] Laura Helbling. "ASCO Response to the ESA REMS," The RPM Report, <www.therpmreport.com> (20 February 2010).

[2] Besarab A, Bolton WK, Browne JK, et al. The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin. N Engl J Med 1998;339:584-90.

[3] Singh AK, Szczech L, Tang KL, et al. Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med 2006;355:2085-98.

[4] Szczech LA, Barnhart HX, Sapp S, Felker GM, Hernandez A, Reddan D, Califf RM, Inrig JK, Patel UD, Singh AK. A secondary analysis of the CHOIR trial shows that comorbid conditions differentially affect outcomes during anemia treatment. Kidney Int. 2010 Feb;77(3):239-46.

[5] Pfeffer MA, Burdmann EA, Chen CY, Cooper ME, de Zeeuw D, Eckardt KU, Feyzi JM, Ivanovich P, Kewalramani R, Levey AS, Lewis EF, McGill JB, McMurray JJ, Parfrey P, Parving HH, Remuzzi G, Singh AK, Solomon SD, Toto R; TREAT Investigators. A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease. N Engl J Med. 2009 Nov 19;361(21):2019-32.)