KIDNEY CARE PARTNERS

April 7, 2011

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Dear Ms. Long and Dr. Koller:

On behalf of Kidney Care Partners, I would like to thank you for the opportunity to comment on the "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" (Proposed Decision Memo). KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers and facilities, and manufacturers dedicated to improving the quality of care for individuals with both Chronic Kidney Disease (CKD) and irreversible kidney failure, known as End-Stage Renal Disease (ESRD).

KCP supports the Centers for Medicare and Medicaid Services' (CMS') decision not to issue a National Coverage Determination (NCD) at this time for ESAs for treatment of anemia in adults with CKD including patients on dialysis and patients not on dialysis. KCP is committed to the goals of safe, appropriate, and high-quality care for ESRD patients. Any anemia management policy, including coverage rules, should be well balanced, well grounded, and well considered. KCP appreciates the Agency's review of the complex issues surrounding anemia management and important questions that have arisen about the optimal use of ESAs in patients with CKD. While we urge CMS to finalize its decision not to issue an NCD, we are concerned that the Proposed Decision Memo makes assertions about the evidence that could be misinterpreted and does not recognize the evidence related to the impact of ESAs on patient quality of life or access to transplantation. Accordingly, we urge the Agency to acknowledge that Local Coverage Determinations (LCDs) in dialysis use would not be appropriate.

I. CMS Should Finalize the Proposed Decision Memo as Drafted

KCP is pleased that CMS did not rush to develop an NCD given the current state of the data. Our members support this approach because it will allow the Food and Drug Administration (FDA) to continue its efforts to evaluate ESAs. Most importantly, it maintains consistency among the various policies that relate to the administration of ESAs. Even though we urge the Agency to maintain the conclusion outlined in the Proposed Decision Memo, we are concerned that the evidence review as described in the Proposed Decision Memo could be read to encourage Medicare contractors to revise their current LCDs for ESA use in pre-dialysis or even initiate restrictions in dialysis use, which could lead to inconsistent treatment standards for patients and have a negative impact on their care.

KCP supports the proposal not to issue an NCD because it maintains consistency among coverage policy, the Quality Incentives Program (QIP), and the ESA Monitoring Policy (EMP), as well as the current FDA-approved label. The anemia management measures adopted as part of the

QIP are based upon the current FDA label, as is the current EMP. Any NCD that would deviate from current policies would lead to inconsistencies in these policies and make compliance with them extremely difficult. Inconsistent policies could create confusion among beneficiaries that could negatively impact their treatment.

Even though we applaud the Agency's proposal not to issue an NCD at this time, KCP is concerned that the Proposed Decision Memo could lead local contractors to initiate restrictive LCDs in dialysis use. A patchwork of LCDs would threaten the quality of care beneficiaries receive and create serious compliance issues for dialysis facilities and providers. The Agency's finding that there is not sufficient data to support an NCD also argues against changing current coverage policies at the local level as well.

Physicians and their patients are in the best position to make decisions about the appropriate treatment protocols based on the emerging scientific data and the individual patient's characteristics and needs. Physicians respond to changes in clinical evidence without unnecessary regulatory intervention. If there were divergent local policies regarding ESA coverage, a beneficiary's access to appropriate anemia management would be based upon coverage policies rather than the physician's best judgment about his/her patient's medical needs. In addition, beneficiaries who travel could find that they would not be able to follow the treatment protocols agreed to with their physicians if they travel to a facility governed by an LCD with different coverage parameters than those in their hometown. Therefore, KCP strongly urges CMS in its final decision memorandum to discourage the adoption of LCDs in dialysis that differ from the FDA-approved label and that would be inconsistent with other CMS policies.

II. KCP Urges CMS To Acknowledge the Importance of ESAs for Beneficiaries' Quality of Life and Limitations in the Data Reviewed about the Impact of ESAs on Access to Transplants

KCP remains committed to patient safety and agrees that CMS should evaluate new evidence that may raise questions about any treatment protocol. When considering such evidence, however, it is critically important that the Agency examine all relevant data as a whole and not focus on only narrow aspects of research. We are troubled that the Proposed Decision Memo does not recognize the important role ESAs play in improving beneficiaries' quality of life and also does not acknowledge the unanswered questions related to the impact of ESAs on beneficiaries' ability to qualify for transplants. We strongly encourage CMS to recognize in the final memorandum that if the Agency sought to issue an NCD in the future it would need to review all available data on the impact of ESAs on beneficiary quality of life and the ability to qualify for transplant.

Policies regarding ESAs should focus on patients and recognize quality of life outcomes as an important consideration. Any statements from CMS regarding the impact of ESAs on patient quality of life should be firmly rooted in beneficiary experiences. Individuals with kidney failure often have severe anemia and experience lower energy in their daily life. In 1991, 84 percent of individuals with kidney failure and on dialysis had a hemoglobin level of 11 g/dL or less; that number fell to 20 percent with the broader prescribing of ESAs by physicians. *See* U.S. Renal Disease System, USRDS 2008 Annual Data Report 93 (2008). Researchers have found a correlation between ESA use and higher energy or less fatigue and with better physical function in both the pre-dialysis and dialysis CKD population. *See, e.g.*, S.R. Gandra, *et.* al, "Impact of erythropoiesis-stimulating agents on energy and physical function in nondialysis CKD patients with anemia: a systematic review," 55 Am. J. Kid. Dis. 519-34 (2009); K.L. Johansen, *et.* al, "Systematic review and

meta-analysis of exercise tolerance and physical functioning in dialysis patients treated with erythropoiesis-stimulating agents," 55 Am. J. Kid. Dis. 535-48 (2010).

Additionally, ESAs have reduced the rate of blood transfusions in the dialysis population. USRDS at 90. Blood transfusions may limit the ability of beneficiaries to qualify for transplant – the only cure for kidney failure. Blood transfusions can sensitize individuals and make it more difficult for them to obtain a transplant. This sensitization may result in longer wait-list times or even disqualification for being considered for a transplant. Although the issue of blood transfusions was discussed during the most recent Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting, the panel did not elicit information about the impact of blood transfusions on the ability of patients to quality for kidney transplant. Additionally, we are concerned that the Proposed Decision Memo does not include the available peer-reviewed literature or available data from national registries that describe the significant risks associated with blood transfusions, most notably, the risk of sensitization.

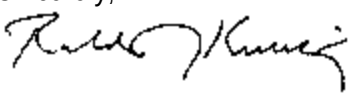
We urge CMS to clarify in any final memorandum the need for further review and evaluation of these two important areas.

III. Conclusion

KCP strongly supports the Agency's decision not to issue an NCD for ESAs for Treatment of Anemia in Adults with CKD Including Patients on Dialysis and Patients not on Dialysis. KCP is committed to the goals of safe, appropriate, and high-quality care for ESRD patients. We recognize that clinical practice has and will continue to evolve. The use of any treatment protocol should promote patient safety and be based upon the best available science. In addition, coverage policies should strive to evaluate all available data and answer all relevant questions that impact the treatment of beneficiaries. The Agency should also strive to ensure that such policies are consistent with quality, payment, and FDA-approval policies as well so that beneficiaries are assured that the care they receive is based upon thoughtful and consistent evaluations and decision-making.

We appreciate your review of these comments and would welcome the opportunity to discuss our concerns in more detail with you and your staff. Please do not hesitate to contact Kathy Lester at 202-457-6562 if you have any questions.

Sincerely,



Ronald Kuerbitz
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