

April 15, 2011

Centers for Medicare and Medicaid Services

RE: Administrative File: CAG # 00413N Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with CKD Including Patients on Dialysis and Patients not on Dialysis

To whom it may concern:

On behalf of the American Society of Nephrology (ASN), a not-for-profit organization of more than 12,000 physicians and scientists dedicated to promoting excellence in the care of patients with kidney disease, thank you for the opportunity to provide comment regarding the proposed decision memorandum for CAG-00413N, Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with CKD Including Patients on Dialysis and Patients not on Dialysis. Foremost among ASN's concerns is the preservation of access to optimal quality of care for patients with chronic kidney disease (CKD) including patients requiring dialysis as well as future candidates for, or current recipients of, a kidney transplant .

ASN supports the Centers for Medicare and Medicaid Services' (CMS) commitment to protecting patient safety and access to the most appropriate treatments by conducting the recent National Coverage Analysis (NCA) and Technology Assessment. These efforts precipitated the proposed decision memorandum that CMS not issue a national coverage determination (NCD) at this time for CAG-00413N, Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with CKD Including Patients on Dialysis and Patients not on Dialysis. ASN has closely followed this process, providing comment letters and presenting expert testimony at all related CMS and Food and Drug Administration meetings. ASN appreciates the opportunities provided to the kidney care community to offer feedback on this important issue.

ASN read with particular interest that CMS noted on page 94 of the proposed decision memorandum ASN's previously stated positions that "current ESAs may be dangerous if used for overly aggressive treatment targets compared with practices that are compatible with current treatment guidelines. [ASN] also believes that continued access to ESAs is required to give both dialysis and non-dialysis patients with CKD, a better chance at receiving and maintaining the function of a kidney transplant." ASN appreciates that CMS incorporated these vitally important points into the proposed decision memorandum and believes the points support the proposal not to issue an NCD.

**ASN supports the proposed decision memorandum that CMS not issue an NCD at this time. Insufficient evidence exists to warrant a change in current policies regarding ESAs for the treatment of anemia in adults with CKD, including patients on dialysis and not on dialysis.**

Furthermore, not issuing an NCD at this time would best allow for CMS reimbursement policy to remain consistent with existing quality measures and pay-for-performance standards in the Medicare ESRD Program. The ESRD Quality Incentive Program (QIP) Final Rule established in July 2010 that dialysis providers will be penalized with lower payments if a higher than specified fraction of patients' hemoglobin concentrations fall outside of the 10 to 12 g/dL range. The recently-implemented ESRD Prospective Payment System also creates disincentives to administer any more ESAs than absolutely necessary to maintain patients' hemoglobin levels within that range. Consistency between CMS quality standards and reimbursement policies is imperative to protect patient access to necessary medications. A final memorandum not to issue an NCD would safeguard patients' access to ESAs.

ESAs are a cornerstone of care for anemia management in patients with kidney disease and have been proven effective for that purpose. Most importantly, nephrologists can treat kidney patients' anemia with ESAs instead of with red blood cell transfusions. The latter can lead to exposure to foreign human antigens, causing immune sensitization. Immune sensitization reduces patients' likelihood of receiving a transplant, and immunosensitized patients who do receive a transplant face higher chances of long-term dysfunction of their kidney. Many patients with CKD will eventually progress to kidney failure, for which transplantation is the best treatment option both from patient quality of life and payor perspectives. Thus, it is of the utmost importance to avoid transfusions in order to not jeopardize these patients' prospects of receiving and maintaining a kidney graft.

Only with administration of ESAs can patients with CKD or ESRD successfully manage anemia while avoiding the hazards of red blood cell transfusions. Continued access to these medications is required to give patients with kidney disease—both on dialysis and not on dialysis—a fair chance at first receiving and then maintaining the function of a kidney transplant. The proposed decision memorandum not to issue an NCD would ensure preservation of patient access to these vital drugs.

In the future, ASN suggests that comparative effectiveness research be conducted to close the evidence gap regarding the optimal role of ESAs in the treatment of relatively severe anemia, while ensuring that patients remain transfusion-free.

In conclusion, ASN believes that no changes to the current CMS policies regarding ESAs are warranted at this time. Maintaining reasonable latitude for patients and their physicians to make individualized decisions about these medications, within FDA guidelines, is crucial. As such, ASN supports the proposed decision memorandum that CMS not issue an NCD.

Again, thank you for your time and consideration. ASN would be pleased to discuss these comments with the CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at [psmedberg@asn-online.org](mailto:psmedberg@asn-online.org).

Sincerely,



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