



MEDCAC Meeting

Testimony of Gail Wick

On behalf of

The American Kidney Fund

4 Minutes

Introduction

Good Morning.

Thank you for convening this MedCAC Meeting today on this aspect of ESA use in CKD patients on and not on dialysis in the setting on kidney transplant graft survival. The American Kidney Fund appreciates the opportunity to submit testimony to the panel on ensuring kidney patients have access to safe and appropriate anemia management care.

My name is Gail Wick and I currently serve on the Board of Trustees of the American Kidney Fund. In addition, I have specialized in the care of patients with kidney disease for 40 years, working in numerous staff and leadership positions in transplantation, in-center hemodialysis, home dialysis and quality improvement. I have also served as president of the American Nephrology Nurses Association twice.

The American Kidney Fund is the nation's leading charitable organization providing treatment-related assistance to kidney patients. Last year, AKF provided over \$155 million in financial assistance to patients on dialysis to help pay for health insurance and dialysis treatment related expenses. Along with providing financial services, AKF works to ensure that kidney patients have access to the quality health care that they need.

Chronic Kidney Disease Management

Chronic kidney disease (CKD) is frequently complicated by anemia and blood transfusion requirements. Anemia is a serious, life-threatening problem affecting many patients with kidney disease.

Prior to the introduction of ESAs, patients suffering from anemia relied heavily on blood transfusions to maintain a healthy red blood cell count. Blood transfusions are necessary for some patients, but carry many risks including disease, infection and iron overload. While helpful with anemia management, blood transfusions in patients with chronic kidney disease have been associated with high panel-reactive antibody (PRA) titers, which can preclude or delay time to kidney transplantation and complicate patient management (Opelz, 2005).

FDA-approved ESAs elevate hemoglobin levels and dramatically decrease transfusion needs for patients with CKD. Lower PRA levels have the ability to allow for a more successful

transplantation process. Aside from the transplantation issue, there are significant health benefits associated with ESA use. With the appropriate dosing and administration of ESAs and control of factors that hinder the body's response to ESA's, patients require less medical attention and hospitalization, are rarely need blood transfusions.

While there has been controversy over dosage administrative practices, it is important to emphasize that each patient receiving dialysis responds differently to the medications used to treat anemia. It is not possible to determine a single dosing regimen that works for all patients at all times. Because of this, it is important that the physician and patient be permitted to decide on an anemia management care plan that is best suited for that patient from a clinical perspective.

Quality of Life Measurements

All dialysis patients have the right to live normal and productive lives. Patients should have access to the best quality of care that allows them to have careers, raise children, and enjoy life.

There have been advances and achievements in anemia management brought about by ESAs. Studies have demonstrated that hemoglobin levels greater than 10 are associated with improved survival and quality of life compared to hemoglobin levels less than 10.

Receiving the proper doses of ESAs has made living a normal life possible for many patients. Additionally, ESAs have reduced the rate of transfusions in the dialysis population. .

Accessibility for CKD Patients

Many kidney disease patients are a fragile population and they often suffer from other co-morbidities such as diabetes and hypertension. Coupled with kidney failure and anemia, these conditions can severely debilitate patients and have a severe impact on their ability to live a quality and productive life.

The Medicare Benefit has provided great new advances in providing patient access to care and successes in fighting kidney disease over the past 10 years. AKF believes that any change in policy should take into consideration its impact on quality patient care and not be centered on incentives.

Additionally, we believe that patients with CKD, but not yet on dialysis, should have access to ESAs when their physicians determine that there is a need. AKF believes that addressing anemia issues prior to dialysis should result in better outcomes for those who later require dialysis and can improve the outcomes of the transplantation process.

Consequently, healthier patients at the onset of dialysis are likely to help drive down first year mortality rates and realize decreased health risks associated with anemia. For example, a 2010 article in the Journal of American Medical Association showed that greater ESA and iron use were associated with decreased mortality risk at lower hematocrit levels, where normally mortality rates are the highest.

Conclusion

In closing, AKF is committed to the goals of safe, appropriate, and high-quality care for kidney patients.

We encourage CMS to continue efforts to ensure that doctors have the flexibility to adjust medications based on patient needs and that patients have access to the medications that provide the best health outcomes.

Thank you for the opportunity to comment on this issue.

CITATIONS

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