



*The Voice of All Kidney Patients*

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September 27, 2004

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**Subject: Medicare Coverage of Erythropoietin**

Dear Dr. Tunis:

On behalf of the American Association of Kidney Patients (“AAKP”), I am writing with comments on the Centers for Medicare and Medicaid Services’ draft policy for “Monitoring of Erythropoietin for Beneficiaries with End-Stage Renal Disease (Link: [www.cms.hhs.gov/coverage/8b4.pdf](http://www.cms.hhs.gov/coverage/8b4.pdf)). CMS’s current EPO policy is governed by PM AB-03-138 ([www.cms.hhs.gov/manuals/pm\\_trans/AB03138.pdf](http://www.cms.hhs.gov/manuals/pm_trans/AB03138.pdf)).

**About AAKP.** The American Association of Kidney Patients (AAKP) ([www.aakp.org](http://www.aakp.org)), founded in 1969, is the nation’s only kidney patient-led and managed education and advocacy organization for people with kidney disease. Each year AAKP serves over 12,000 members and, through its programs, hundreds of thousands of other Americans who have either lost kidney function (and live with dialysis or transplant) or have serious chronic kidney disease (CKD). The *average* life expectancy for individuals following initiation of dialysis therapy is short, about 5 years. But AAKP’s membership includes many long-term dialysis survivors (in some cases exceeding 25 years), who live full and productive lives only by aggressive attention to their health care, a core mission of AAKP. Indeed, most kidney patients face not only the challenge of kidney disease, but other medical conditions as well, such as diabetes and hypertension.

**General Principles.** AAKP reviews proposed government policies with respect to several core principles: Will a proposed policy improve access and quality of care, and does the proposed policy respect the principle that *a physician and patient make a joint determination of the care plan best suited for that patient?*

**Comments.** AAKP submits the following comments and questions in response to the draft policy:

American Association of Kidney Patients  
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1. AAKP commends CMS for the deliberate and thoughtful process of fashioning a revised erythropoietin monitoring policy, and for providing patients and other interested parties with the opportunity to comment. On its face, the draft policy provides new flexibility and stability in anemia management. The hematocrit level that triggers a medical review has been raised above current policy, and mandatory partial payments have been provided for hematocrit range above current medical review triggers.

2. Clinical Data Supporting Overutilization Allegations. The proposed policy states that one prompt for the revised policy is to remove “some of the financial incentives that currently promotes overutilization of the drug.” Such allegations are properly a serious matter, but AAKP again poses the “evidence-based” question raised in our January 2004 comments, but not answered in the draft policy: What clinical studies demonstrate that dialysis patients – either nationally or regionally – are receiving more erythropoietin than necessary to maintain an appropriate hematocrit level, or that inappropriate EPO prescribing by physicians is the driver for increased EPO spending?

AAKP also asked this question in our January comments, but again not addressed in the explanation to the draft policy: Why won't the new "basic case-mix adjusted composite rate" mandated by MMA remove any current law financial incentive for overutilization of EPO? That new rate includes, *inter alia*, removal of the “profit” on Part B covered ESRD drugs through transfer of dollar difference (“spread”) between acquisition and Medicare payment rates for separately billed drugs and biologicals (including erythropoietin) to the composite rate.

3. Medical Justification and Appeals. The draft policy called for medical justification to receive Medicare payment when erythropoietin values fall above certain stated dose and hematocrit limits. Based on existing data, what percent of claims would trigger medical justification? What is the process for establishing medical justification and requesting an appeal – who may appeal, in what form, may payment continue during the appeals process, and are there are requirements for timeliness of response to an appeal?


4. Uniformity of Part B Covered Drug Policies. CMS covers other expensive drugs and biologicals, including the use of erythropoietin in cancer patients. What other Part B covered drugs and biologicals, if any, are subject to a CMS monitoring policy?

5. Future Changes to Monitoring Policy. Does CMS have a schedule to revisit the erythropoietin monitoring policy?

As always, AAKP appreciates the hard work of CMS personnel involved in improving the lives of kidney patients. If you require further information regarding this letter, please contact Kris Robinson, AAKP's Executive Director, at (800) 749-2257.

Thank you in advance for considering AAKP's comments.

Sincerely,



Brenda Dyson  
President

cc: Brady Augustine  
Jackie Sheridan  
Barry Straub, M.D.