DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality

September 22, 2003

To Those Interested in Medicare Coverage of Erythropoietin:

Medicare coverage for erythropoietin (EPO) is consistent with the Kidney Dialysis Outcome Quality Initiative (K-DOQI) guidelines and the Food and Drug Administration (FDA) approved indications. K-DOQI recommends management of anemia within a target hematocrit range of 33 to 36 percent. FDA has approved EPO to treat patients with anemia when it is used to raise the blood hematocrit to a target range of 30 to 36 percent (or the blood hemoglobin to a range of 10 to 12 grams per deciliter). Neither entity recommends the use of EPO for raising hematocrit levels above 36 percent.

Medicare pays over a billion dollars annually for EPO administered to end stage renal disease (ESRD) patients, with aggregate payments for the drug doubling between 1998 (550 million) and 2001 (1.1 billion). The law provides a payment formula of $10 per 1000 units of EPO administered to ESRD patients. There is concern that this payment formula may result in some patients receiving more EPO than is required to maintain their hematocrit level within the target range. If so, Medicare spending on EPO may be higher than necessary without resulting in optimal patient benefit.

In an effort to reduce potential EPO over-utilization, CMS issued a policy in 1997 instructing Medicare contractors to monitor the hematocrit levels of ESRD patients. This policy provided for pre-payment review of EPO claims and denial of claims when the 90-day average hematocrit level exceeded 36.5 percent. Through discussions with clinicians and industry representatives, we learned that normal fluctuations in hematocrit levels make it extremely difficult to maintain patients at the upper end of the target range without exceeding the upper boundary of the range.

Over the past three years, CMS has issued temporary instructions to implement a revised policy that allows more flexibility at the upper boundary of the hematocrit range. The current instructions prohibit Medicare contractors from performing pre-payment review of EPO claims. Contractors are instead instructed to perform post-payment review using a 90-day average hematocrit level of 37.5 percent to trigger further medical review. It has come to our attention that this policy may be difficult to implement because of the administrative burden of continually averaging hematocrit levels. CMS has also been asked to provide more precise definitions for several critical terms in the existing Program Memorandum AB-02-100. In addition, we have been asked to revise the point at which facilities may initiate EPO therapy.

For these reasons, CMS will undertake a thorough review of our current policy on EPO utilization in ESRD. We have established a schedule for this re-evaluation (see table below). In the meantime, we have reissued the temporary policy in Program Memorandum AB-03-138. We invite interested parties to send us scientific evidence related to EPO dosing and hematocrit/hemoglobin levels that will assist us in the development of a clinically and scientifically robust policy that will ensure appropriate administration of EPO in ESRD patients.

Time Period	Activity
Letter Issuance Date – November 30, 2003	The public is invited to submit scientific evidence related to EPO dosing and hematocrit/hemoglobin levels. Parties submitting data are invited to also schedule meetings to present data and provide verbal explanations of their analysis if they so desire.
December 1, 2003 – February 1, 2004	CMS staff will analyze data submitted. We may supplement the submittals with data from the USRDS or CMS data sources such as national claims history files, performance measurements, REBUS, etc.
March 1, 2004	CMS will circulate a draft policy for comment.
May 1, 2004	CMS will issue a final revised policy or a memorandum announcing the decision regarding national monitoring of EPO for ESRD patients.

We encourage all interested experts and stakeholders to participate in this public process by submitting scientific evidence related to EPO dosing, hematocrit levels and ESRD patient outcomes. Interested parties can submit information to Steve Phurrough, MD, MPA, Director, Coverage and Analysis Group, Centers for Medicare and Medicaid Services, Mail Stop C1-09-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. If you have questions or wish to schedule an appointment to discuss your submittal, please contact Jackie Sheridan-Moore at 410-786-4635 or by email at jsheridan@cms.hhs.gov.

Sincerely,

/s/

Sean R. Tunis, MD, MSc.
Director, OCSQ
Chief Medical Officer, CMS