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

Office of Clinical Standards and Quality

To Those Interested in Medicare Coverage of Erythropoietin:

The Centers for Medicare & Medicaid Services (CMS) is proposing a revised policy for monitoring claims for erythropoietin (EPO) for end stage renal disease (ESRD) patients. Over the next 60 days we invite interested experts and stakeholders to submit comments on the proposed policy (see draft below) and its potential effects on patient outcomes.

You can submit your comments electronically using our Contact Us resource. Be sure to specify EPO coverage in the subject line. You can also mail your comments to the address below:

Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
Attn: EPO Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 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 e-mail at jsheridan@cms.hhs.gov.

Sincerely,

/s/

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

Centers for Medicare & Medicaid Draft Policy
Monitoring of Erythropoietin for Beneficiaries with End Stage Renal Disease

Background

Erythropoietin (EPO), a drug manufactured and distributed by Amgen, is used for anemia management of patients with renal disease. It is FDA indicated to maintain hematocrit levels within a target range of 30-36 percent.

The current methodology for monitoring EPO claims was implemented with limited scientific analysis. It limits monitoring of EPO to post-payment review based on a 90-day rolling average of claims. The target to trigger action is 37.5 to provide recognition of naturally occurring variability in hematocrit levels. Additionally, higher levels could be maintained upon medical justification by the treating physician. The revised methodology was issued through a series of temporary instructions.

In the fall of 2003, CMS solicited scientific information from the ESRD community in order to develop a permanent evidence-based policy for EPO monitoring. The scientific literature supported the fact that patients with hematocrit levels within the target range had better health outcomes than those below the target level. The data also supported the fact that there is considerable natural variability in individual patient hematocrit levels making it difficult to consistently maintain a hematocrit within the narrow range of 33-36.

The Medicare Modernization Act of 2003 provided for a change in the payment methodology for drugs under Medicare. Effective January 1, 2005, Medicare will begin a new payment for EPO based on acquisition costs, removing some of the financial incentive that currently promotes overutilization of the drug

Policy

The Dialysis Outcomes Quality Initiative recommends a threshold hematocrit value range of 33 to 36 percent. However, due to naturally occurring variability in hematocrit levels, it is very difficult to maintain a hematocrit within this narrow range without occasionally exceeding the target ceiling of 36. Further, starting and stopping EPO therapy can lead to dramatic dips in hematocrit levels that may require high doses of EPO to achieve the target level again. Thus, appropriate utilization of EPO should be monitored by considering both the hemoglobin/hematocrit level and the dosage. Contractors will conduct medical review on EPO claims for ESRD patients using the following methodology.

- Claims for EPO with hemoglobin levels below 13 (or hematocrit of 39) on a single claim should not be targeted for review.
- Claims with hemoglobin levels between 13.0 and 13.9 (or hematocrit of 39 to 42) should be reviewed if the patient has received a monthly dose of EPO greater than 40,000 IU. If the higher dosage has not been medically justified, contractors should limit payment to the 40,000 IU level.
- Claims with hemoglobin levels 14.0 or greater (or hematocrit equal to or greater than 42) should be reviewed if the patient has received a monthly dose of EPO greater than 20,000 IU. If the higher dosage has not been medically justified, contractors should limit payment to the 20,000 IU level.

Facilities are free to monitor red blood cell levels using either hematocrit or hemoglobin. If hemoglobin is used, the facility must convert to hematocrit by multiplying the test result by 3 to report on the claim.

These hematocrit requirements apply only to EPO furnished as an ESRD benefit under §1881(b) of the Social Security Act (the Act). EPO furnished incident to a physician's service is not included in this policy. Carriers have discretion for local policy for EPO furnished incident to physician services.