MEDICARE PART A BULLETIN

May 23, 1997 ESRD Medicare Bulletin E-28

TO: All Medicare End Stage Renal Disease (ESRD) Providers

FROM: Andy DePirro, Director, Program Relations

SUBJECT: HCFA CLARIFICATION OF HEMATOCRIT LEVELS FOR ERYTHROPOIETIN (EPO)

ATTENTION MEDICARE BUSINESS OFFICE: Please distribute to all appropriate health care facility personnel.

ESRD Medicare Bulletin E-26, dated April 1, 1997, notified providers of instructions from the Health Care Financing Administration (HCFA) regarding processing and payment calculation changes for End Stage Renal Disease (ESRD) patients receiving erythropoietin (EPO). These revised instructions are effective for services performed on and after July 1, 1997, and provide for calculating on a rolling average hematocrit for claims where the hematocrit level of the patient exceeds 36%.

HCFA has requested this clarification of policy be published to all ESRD providers.

Subsequent to the release of the revised instructions, HCFA has received numerous contacts requesting clarification of the medical review policies related to EPO therapy. Under previous policy, fiscal intermediaries were authorized to make claim payment for EPO therapy where the hematocrit exceeded 36%, if supported by medical documentation. The revised policy states that such medical review procedures would not be permitted under the new rolling average audit procedures, and instructed intermediaries to deny claims exceeding an average hematocrit of 36.5%. However, the instructions did not explicitly state that the medical review policy in Section 3907.2 of the Medicare Intermediary Manual (HCFA Publication 13-3) was altered.

For this reason, HCFA has issued Program Memorandum AB-97-8 (HCFA Pub 60 A/B; Rev. AB-97-8; 05-97; Retrieval Title: AB-97-8.60) to clarify and state explicitly that intermediaries are not to review claims exceeding an average hematocrit of 36.5%. Instead, these claims are to be automatically denied as not reasonable and necessary. Based on considerable research of the literature and discussions with a noted hematologist at the National Institutes of Health, HCFA is not able to confirm the allegations that there is a medical justification for maintaining sustained hematocrit levels above 36%.

Although HCFA has received several comments alleging that there is a medical justification for higher hematocrits in selected cases, these concerns were generalized and anecdotal. None of the commenters were able to submit empirical evidence demonstrating the ill effects of maintaining a hematocrit level of 36%. This is only slightly below the average hematocrit level of the normal female, which is 37%. Moreover, research presented to the Food and Drug Administration (FDA) in support of approved labeling of usage of EPO was limited to 36%.

HCFA notes that research related to maintenance of higher hematocrit levels was discontinued, presumably due to adverse consequences to the test population. Therefore, HCFA has instructed intermediaries not to review EPO claims for medical justification of higher hematocrit levels.

Similarly, HCFA has received numerous comments alleging the need for higher hematocrit levels for persons residing in high altitudes. Commenters alleged that the effect of altitude on blood composition necessitates maintaining patients at higher hematocrit levels.

In analyzing these concerns, HCFA reviewed data from ESRD patients receiving EPO therapy. The hematocrit levels of patients in high altitude states, such as Colorado and Utah, were compared with the national average. It was learned that the average hematocrit of patients in the six high altitude states was 32.8%, while the national average was 32.2%. Further, HCFA found that the percentage of patients with hematocrits exceed 36% in high altitude states was nearly identical to that of the national average, except for those two states where the contractor had historically authorized payment for higher hematocrit levels without justification.

However, the hematologist from the National Institutes of Health advised HCFA that, in theory, exceedingly high altitudes could necessitate the need for maintaining higher hematocrit levels in order to avoid adverse health factors. Consequently, HCFA is amending the policy to allow for a rolling average hematocrit of 39.5% for those beneficiaries who reside in altitudes at or above 6,000 feet. Intermediaries are therefore instructed not to deny claims for payment of EPO for a beneficiary residing at an altitude at or above 6,000 feet until the 90-day rolling hematocrit average exceeds 39.5%.

HCFA will be issuing revisions to the manualized instructions regarding EPO in the near future.

Questions regarding this bulletin may be addressed to the Medicare Part A Customer Service Department by calling 904/355-8899.