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October 6, 2004

Sean R. Tunis, MD, MSC
Director, OCSQ
Chief Medical Officer
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Attn: EPO Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Tunis:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on the Centers for Medicare & Medicaid Services' (CMS) revised policy for monitoring claims for erythropoietin (EPO) for end-stage renal disease patients (ESRD). We appreciate the ongoing efforts of the CMS staff to administer and improve payment for ESRD services, particularly considering the competing demands on the agency.

CMS is proposing to implement a national policy that will be used by its contractors when paying claims for EPO. The proposed policy uses a combination of a patient's hematocrit level and EPO dosage amounts to trigger contractor review of the medical justification for the EPO dosage. If the dosage is found not to be justified, payments are reduced to lower dosage levels. CMS strived to create a permanent policy that accounts for the naturally occurring variability in patients' hematocrit levels. The proposed policy does not set an upper limit for EPO dosing; rather it links dose and outcome.

To develop this proposed policy, CMS used an evidence-based process and solicited comments from the scientific and provider communities. An evidence-based process uses the best available medical and scientific evidence; such a process is already used to evaluate items and services when making national coverage decisions. MedPAC endorses the agency using an evidence-based approach to develop and refine Medicare's payment policies.

Implementing a national policy is an important step to ensure that EPO is appropriately used. Some evidence reported by MedPAC and other researchers suggests that in certain instances, separately billable dialysis drugs, including EPO, are not being furnished efficiently. Ultimately, broadening the dialysis payment bundle to include EPO, other separately billable drugs, and other commonly furnished and needed services will provide strong incentives for providers to control the costs of services. MedPAC recommended broadening the bundle in March 2001 and reiterated this recommendation in October 2003.

After implementing the new policy, CMS should evaluate its effect on the hematocrit levels of ESRD patients to ensure that patients receive clinically appropriate care. The agency could, for example, compare hematocrit levels of specific patient subgroups before and after implementing the new policy.

MedPAC appreciates the opportunity to comment on policy proposals introduced by CMS. The Commission also values the willingness of CMS staff to provide relevant data and to consult with us concerning technical policy issues. If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth,
Chairman

GH/nrc