

February 29, 2000

Medicare Coverage Advisory Committee
c/o Sharon K. Lappalainen, Executive Secretary
Office of Clinical Standards and Quality
Health Care Financing Administration
7500 Security Boulevard
Mail Stop S3-02-01
Baltimore, Maryland 21244

Dear Ms. Lappalainen:

The American College of Physicians–American Society of Internal Medicine (ACP–ASIM), representing over 115,000 physicians who specialize in internal medicine and medical students, wishes to offer its comments and concerns on the draft report of the subcommittee of the Medicare Coverage Advisory Committee’s (MCAC) Executive Committee entitled: *Recommendations For Evaluating Effectiveness*. ACP–ASIM is generally supportive of these recommendations, but feels it critical that the MCAC strike a healthy balance between assuring a coverage review process which is credible and defensible from a scientific viewpoint, yet not so mired in technical detail that final coverage decisions are unreasonably delayed.

ACP–ASIM is very supportive of the draft report’s objectives: that important clinical coverage decisions be reviewed on the basis of sound and objective clinical evidence by the MCAC’s six medical specialty panels, that there be consistency in the nature and quality of data reviewed by the panels, and that there be a standardized methodology and format for panels to present their recommendations to the MCAC Executive Committee, thereby allowing the Executive Committee to make uniform, high quality, and scientifically defensible coverage recommendations to HCFA. We also support the draft report’s recommendation that the MCAC only focus on the “clinical and scientific questions around the medical effectiveness of new items and services, and the comparative effectiveness of new items and services relative to existing alternatives,” and that the MCAC not address questions “about dollar costs of new items or services.”

We are impressed with the amount of scientific rigor the draft report proposes for assessing the adequacy of clinical evidence related to a new item or service, and calculating the magnitude of the health benefit such coverage would have on the Medicare population. We do wish to raise some technical concerns under the draft report’s section on Evaluation of Evidence. On page three, the discussion of potential sources of bias has some noteworthy omissions, including double-blinding, perfect compliance, adequate length of follow up, distinct treatment separation, and inappropriate statistical analysis. Imperfections in any of these would permit bias to enter into a randomized - controlled clinical trial and thus make the results less valid for the population under study, and thus difficult from which to generalize. We also feel the draft report’s recommendation on page four, that MCAC panels be required to “describe

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possible sources of bias and explain why a panel decided that bias does not account for the results,” should be applied in all coverage decisions, not just the limited circumstance of uncontrolled studies described on page four. Also, on page five, where seven categories of size of health effect are presented, there appears to be one category omitted, which we would recommend the addition of—“more effective but with disadvantages.”

In summary, ACP–ASIM believes it is vital that coverage decisions remain in the hands of the medical experts comprising the panels of the MCAC, and that the credibility of this body will depend on striking a balance between scientific rigor and decision-making which is not bogged down in process. Decisions reached by the MCAC must be based on the best mix of objective data and professional judgement possible, and lead to coverage recommendations that have a compelling weight of evidence, yet are rendered in reasonable timeframes to avoid work backlogs which might undermine MCAC effectiveness and credibility.

ACP–ASIM supports the MCAC coverage decision process and welcomes the opportunity to contribute to its evolution. We believe the time spent now will pay great dividends in the future, and that the MCAC’s evidence-based decision-making model will soon become one of which we can all be proud.

Sincerely,

Whitney W. Addington, MD, FACP
President