

Response to CMS Request for Comments on the Effectiveness of Pharmacogenomic Testing for Warfarin Metabolism in the Medicare Beneficiary Population

The CAP believes there is ample evidence for the clinical validity and utility of pharmacogenetic testing for warfarin metabolism in predicting some of the variability in patient's response to warfarin therapy. The improved outcomes related to pharmacogenetic testing include a decreased time to achieving optimal therapeutic range of warfarin, and a decreased time outside the therapeutic range, with the consequent expected benefits of fewer major hemorrhagic and thrombotic events. A recent report from the Brookings Center summarizes the likely improvements in outcomes and health care cost savings in pursuing this strategy.¹ Coverage of pharmacogenomic testing is essential to achieve the HHS Secretary's vision of personalized health care and necessary to facilitate data collection on the benefits of this technology. The Secretary's report² on Personalized Health Care and others have identified lack of coverage and reimbursement for genetic and genomic tests as an obstacle to this vision. Pharmacogenetic testing for warfarin dosing is one of many such tests that can result in improved outcomes and reduced costs.

As stated above, CAP believes that there is already ample evidence justifying appropriate use of pharmacogenomic testing for warfarin, as evidenced by the change in the drug label as decided by the FDA to include the pharmacogenetic information based on current evidence. Currently, prospective outcomes clinical trials on the comparative effectiveness of pharmacogenetic testing for warfarin dosing are underway, sponsored by the NHLBI and being coordinated by Dr. Stephen E. Kimmel at the University of Pennsylvania School of Medicine and involving 12 clinical sites. We anticipate that the results of these trials will corroborate and enhance the available data supporting the implementation of this testing. Alternatively, if CMS determines that the current evidence from completed studies is insufficient to reach a decision, CMS may wish to delay consideration of a National Coverage Analysis until completion of prospective clinical outcomes trials currently underway.

¹ Andrew McWilliam, Randall Lutter, and Clark Nardinelli, Health Care Savings from Personalizing Medicine Using Genetic Testing: The Case of Warfarin. AEI-Brookings Joint Center for Regulatory Studies, November 2006.

² <http://www.hhs.gov/myhealthcare/news/phc-report.pdf> Accessed 8/16/08