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Reed Tuckson, M.D., Chair  
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**May 6, 2005**

### **Comments on the Draft Coverage and Reimbursement**

Dear Dr. Tuckson and Members of the SACGHS Committee,

The Association for Molecular Pathology (AMP) thanks the committee for the opportunity to provide comments on the draft report, "Coverage and Reimbursement of Genetic Tests and Services." First and foremost, AMP applauds the committee on the thoroughness and thoughtfulness of the report. Such a complete review and assessment of the issues related to the coverage and reimbursement of genetic services is remarkable and highly valuable to the healthcare community.

The Association for Molecular Pathology is an international, not-for-profit educational society representing over twelve hundred physicians, doctoral scientists, medical technologists and professionals who perform and support molecular genetic testing as well as other tests based on nucleic acid technology. The AMP membership is from academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the *in vitro* diagnostic industry. In this capacity, AMP members are involved in every aspect of genetic testing: performance and interpretation of genetic tests, basic and translational genetic research and genetic education. For the last several years AMP has provided national leadership to advance the safe and effective use of molecular genetic testing in health care.

AMP's comments will focus on three major points, Review of the Molecular CPT Codes by CMS, the Definition of Genetics Tests, and Coverage and Reimbursement for Genetic Counseling and Medical Genetics Services, followed by more specific points on items throughout the draft report.

### **Recommendation to Review of Molecular CPT Code Reimbursement**

AMP strongly supports the proposal in the Coverage and Reimbursement document to request CMS to review and revise reimbursement for molecular CPT codes. At the March 2004 SACGHS meeting, Dr. Andrea Ferreira-Gonzalez, as an AMP officer, presented that national and local reimbursement levels for the molecular CPT codes are inadequate to cover the cost of performing genetic tests. As we advance irreversibly toward molecular medicine as standard of care, genetic tests will play an increasingly prominent role in disease diagnosis, prognosis and management. As the number of available genetic tests and their use in routine diagnostics grows, laboratories will not be able to continue absorbing the losses associated with genetic testing, as they do today. AMP expends extensive effort and resources to urge CMS to ameliorate the current state of insufficient reimbursement, which threatens to restrict access to these important tests, with concomitant negative impact on patient care. We strongly support the SACGHS recommendation for CMS to review and revise reimbursement for molecular CPT codes. AMP, through its

resources and knowledge of this subject stands ready to assist CMS in carrying out this recommendation. While this effort will assist in the short term with the inadequacy of reimbursement for molecular tests, AMP will continue to work with other professional groups to look more globally at the adequacy of the current molecular coding system, addressing issues such as the level of automation of testing, the volume of testing and the ability to represent in CPT codes the testing being performed. We hope this process will allow proposal of more global revisions to coding for this high growth area of Clinical Laboratory Medicine. We ask that these groups be given the opportunity to bring future proposals to SACGHS, for your edification and for potential support.

### **The Definition of a Genetic Test**

AMP supports the latest revision of the section "What are genetic/genomic tests and technologies?" This description begins to refine the issue that the term "genetic/genomic tests" has different meanings in different settings. The fact that this was necessary demonstrates that precise definitions need to be formulated and adhered to, and that it is likely that we will need thoughtful categorization of different kinds of genetic testing. One specific concern is the inclusion of pharmacogenetics testing in this discussion, since this testing identifies allelic variants that are not associated with disease, but only affect drug metabolism. Only in the presence of an external challenge (drug) will health risks be apparent

### **Coverage and Reimbursement for Genetic Counseling and Medical Genetics Services**

AMP members performing genetic tests work closely with genetic counselors and medical geneticists. Medical geneticists and genetic counselors provide information to patients and their families about the specific genetic disease, genetic testing options, the meaning of test results and various additional testing and treatment options. These types of genetic services are time intensive and are not adequately reimbursed at this time. AMP strongly supports all the recommendations regarding coverage and reimbursement for genetic counseling and medical genetics services.

### **Specific Points**

- Page 22. In focusing on people 65 and older, while the clinical validity may be different for this population (based on age of onset, etc), the analytical validity for inherited disease tests remains the same regardless of age.
- Page 24. Please clarify the term "Prevalence of the gene variant." Does this mean disease prevalence, that would drive the ordering of the test, or the common genetic variant(s) seen in the population or all possible variants?
- Page 40. The new genetic modifiers are raising more questions than they answer. If the purpose of the molecular CPT Modifier Codes is to clarify the type and purpose of testing, then one modifier code can still apply to several different levels of testing for the same disease. For example, in cystic fibrosis (CF), testing can be for one mutation only (when documented that this is the familial mutation), for 23-80 mutations for a CF panel, and for full gene analysis for an affected individual when two mutations are not detected by the panel or for atypical CF patients. Will these levels of testing be misunderstood when using the CF modifier?
- Page 46. Education of insurance companies is a key factor in greater use and acceptance of genetic tests in clinical practice. Several years ago, Blue Cross/Blue Shield of Utah had a policy of not covering any genetic tests, since these tests were considered research. Through education by physicians, laboratorians and genetic counselors, Blue Cross/Blue Shield of Utah has reviewed its policy and will be including genetic tests, for at least a number of common disorders, in 2006.
- Page 47. AMP asks that SACGHS give full consideration to the negative impact of exclusive licensing and enforcement practices for gene patents on the future of genetic testing.

We understand that SACGHS has set this as a high priority but has decided to wait for the National Academy of Sciences study of intellectual property related to genomics and proteomics. We urge you to promptly set this as an agenda for the SACGHS as soon as the report is available.

Page 47. The cost of testing is directly related to test volumes. The ability to “batch” samples decreases the cost dramatically, while rare testing performed on one specimen at a time are very expensive.

On behalf of AMP, I thank you for the opportunity to comment on the draft report on Coverage and Reimbursement of Genetic Tests and Services. AMP remains available to the SACGHS to assist with or provide information for your thoughtful deliberations and important work.

Sincerely,

A handwritten signature in black ink that reads "Mark A. Lovell, M.D." The signature is written in a cursive style with a large, sweeping initial 'M'.

Mark A. Lovell, M.D.  
President, Association for Molecular Pathology