Comments to CMS regarding Pharmacogenetic Testing of Warfarin Response (CAG-00400N)

The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 1,500 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Since the beginning of our organization we have dedicated ourselves to the development and implementation of molecular diagnostic testing, which includes genetic testing in all its definitions, in a manner consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. Our members populate the majority of clinical molecular diagnostic laboratories in the United States. They are frequently involved in the origination of novel molecular tests, whether these are laboratory developed or commercially developed.

We agree with CMS that coverage decisions should be informed by published evidence from outcome related clinical trials. For some pharmacogenetic tests, such data is, we believe, imminent, and we recommend that National Coverage Determinations (NCDs) not be entertained at this time. For example, preliminary evidence suggests that genotyping for warfarin sensitivity is likely to have clinical benefit if certain criteria are met, as described in *J Thromb Haemost*. 2008 Jul 7. [Epub ahead of print] PMID: 18627440. We are encouraged by results thus far and are aware of ongoing larger studies, *e.g.,* the NHLBI Clarification of Optimal Anticoagulation through Genetics (COAG) trial (PI: Stephen Kimmel, MD). However, these larger studies must be completed and evaluated by the appropriate agencies and professional organizations prior to a national coverage decision by CMS.

Similarly, NCD's for gene expression profiling tests would be premature without due consideration of test specific outcomes data. Hence, we recommend that CMS exercise restraint in the consideration of global coverage decisions for this category of tests at this time.

AMP has been working with carrier/contractor medical directors to facilitate local coverage decisions. We are committed to providing expertise to CMS for this and other coverage decisions that involve molecular testing at national and local levels. Please contact either Jean Amos Wilson, PhD, Professional Relations Committee Chair at jamoswilson@bhlinc.com, or Victoria M. Pratt, PhD, Clinical Practice Committee Chair at victoria.m.pratt@questdiagnostics.com, for additional information.

Sincerely,
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