



**Association for Molecular Pathology**  
*Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology*  
9650 Rockville Pike, Bethesda, Maryland 20814  
Tel: 301-634-7939 • Fax: 301-634-7990 • Email: [amp@asip.org](mailto:amp@asip.org) • [www.amp.org](http://www.amp.org)

September 02, 2008

Niles R. Rosen, MD  
Medical Director  
National Correct Coding Initiative  
Correct Coding Solutions, LLC  
P.O. Box 907  
Carmel, IN 46082-0907

Dear Dr. Rosen:

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.

Attached are the comments of the Association for Molecular Pathology (AMP) on the Phase VIII proposed Medical Unlikely Edits (MUEs) for laboratory and pathology services. We offer revised MUEs for most of the molecular diagnostic technique codes (83890-83914). The absence of a comment on a proposed MUE for non-molecular codes should not be construed as affirmation.

We emphasize the inherent difficulty in proposing MUEs for the molecular diagnostic codes. These are procedural codes, and in themselves cannot be related to any specific analytes or clinical circumstances. The same patient on any one day may have need for any number of molecular tests, necessitating the usage of these molecular procedural codes multiple times. It is simply not possible to determine medical necessity for these codes, and in truth, no *a priori* limits can be made. Consequently, we strongly suggest that CMS reconsider this endeavor to set MUEs for these codes.

We did give due consideration to determining MUEs for these codes based on historical claims data. In your letter of July 1, you emphasized that the proposed MUEs were, in part, derived from claims data from 2006. The field of molecular diagnostics is evolving extremely rapidly and the testing available in 2006 does not reflect the number and complexity of

molecular tests available in 2008, and even less so for 2009 and beyond. We view this approach as inherently erroneous and impractical.

While we sincerely believe that the molecular code series should not be subject to specific MUEs, we have provided our own recommendations, should CMS determine it necessary to define MUEs for these codes. Our rationale for these recommendations comes from examples of established, clinically valid tests in current usage. The fact that we can cite multiple examples for most of these codes, each for very different clinical circumstances, emphasizes the futility in trying to set MUEs for procedural codes. We do believe that these examples establish absolute minimum MUEs, and we fully expect that higher numbers are within reason and may be seen soon.

We appreciate the opportunity to comment on these proposed edits, and would be happy to offer further information regarding our responses. If so, please feel free to contact Jan Nowak, PhD, MD through the Association for Molecular Pathology at [mwilliams@amp.org](mailto:mwilliams@amp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Gregory J. Tsongalis". The signature is fluid and cursive, with a prominent initial "G" and a long, sweeping tail.

Gregory J. Tsongalis, PhD  
President