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RE: Draft Local Coverage Determination – MolDX: HLA-B*15:02 Genetic Testing (DL36145, DL36149)

Dear Dr. Lurvey:

Thank you for the opportunity to comment on DL36145, DL36149. AMP (Association for Molecular Pathology) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

The College of American Pathologists (CAP) is a national medical specialty society representing more than 17,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

Members of both AMP and CAP are experts in molecular pathology and the implementation of this coverage policy will directly impact their practices. We are submitting joint comments because at this time both of our organizations share the same concerns regarding this draft LCD, and we request that Noridian consider implementing the consensus recommendations outlined in this letter.

First, we thank you for your decision to cover HLA-B*15-02 under limited circumstances. We agree with your determination that this test is medically necessary, but believe that the reimbursable population should be increased to include people of Oceanian, as well as Asian, descent. As you can see in the chart below, Oceanian's have an unusually high prevalence of allele frequencies for HLA-B*15-02. For this reason, we believe it is necessary to reimburse the HLA-B*15-02 test for this population.

We respectfully ask that you consider these comments which were prepared by a consortium of providers in the Noridian jurisdiction as well as other members of AMP and CAP, laboratory directors, staff and consultants who provide service to Medicare beneficiaries covered by Noridian. We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this draft LCD. Please direct your correspondence to Mary Steele Williams, AMP Executive Director, at mwilliams@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@amp.org.

Sincerely,

Association for Molecular Pathology
College of American Pathologists

Supplemental Table S1. Worldwide Allele Frequencies1 of HLA-B*15:02- Summary by Race/Ethnic Group[2]

Race/Ethnic Designation	Allele Frequency	Sample Size
African	0.0	271
Non-Caucasian American	0.0039	371
East Asian	0.043	14,397
European	0.000057	30,640
Middle Eastern	0.0045	491
Oceanian	0.107	201
South/Central Asian	0.0134	235
[1]Average allele frequencies are reported based on the average from the actual numbers of subjects with each allele reported in multiple studies.		
[2]Race/ethnic group designations correspond to those indicated in Supplemental Table S2.		

[1] Clinical Pharmacogenetics Implementation Consortium (CPIC) Guidelines for HLA-B Genotype and Carbamazepine Dosing. *Clinical pharmacology and therapeutics.* 2013. Leckband Susan G, Kelsoe John R, Dunnenberger H Mark, George Alfred L, Tran Eric, Berger Reisel, Müller Daniel J, Whirl-Carrillo Michelle, Caudle Kelly E, Pirmohamed Munir