November 5, 2014

Dear CPT Advisory Committee:

I am writing on behalf of AABB in support of creating a CPT Tier 1 code for blood group genotyping. AABB is a not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health by delivering standards, accreditation and professional educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of approximately 1,800 institutions and 8,000 individuals, including physicians, nurses, medical technologists and other professionals. Recognizing the importance of blood group genotyping, AABB has developed Standards for Molecular Testing for Red Cell, Platelet and Neutrophil Antigens.

In the last few years, genotyping for human erythrocyte antigens has become increasingly common in transfusion medicine and evidence in the literature supporting its clinical utility continues to accumulate. RBC genotyping has many applications in blood donor testing, including transfusion of patients requiring chronic transfusion support (e.g. sickle cell disease) and determining the risk of hemolytic disease of the fetus/newborn (HDFN) in mothers with difficult-to-interpret serologic results.

Frequently transfused individuals are at higher risk of receiving incompatible blood and resulting adverse events than patients who require only rare or single transfusions. Individuals who may require ongoing and frequent transfusion support include patients with sickle cell disease and thalassemia, as well as some oncology and renal patients, among other groups. These frequently transfused patients require more thorough blood typing to avoid incompatibilities, which can result in life-threatening and costly adverse reactions.

Although all blood units are tested for ABO, Rh, and infectious disease, frequently transfused individuals require extended blood group antigen testing. Current serologic typing techniques are based on antisera for less-common blood groups. These tests can be time-consuming and there are certain circumstances where the precision of serology is questionable. For example, the accuracy of serology is limited in typing chronically transfused patients or patients with autoimmune hemolytic anemia, antigen typing where no commercial antisera are available, and in the prenatal determination of fetal risk of HDFN when there are discordant RhD results. These clinical scenarios are not uncommon. For example, over half of patients for whom extended phenotyping is indicated may not be able to be typed due to recent transfusion or autoantibodies.

In addition, blood group genotyping can provide more accurately-typed blood for patients at a fraction of the time it takes to serologically type the donor and patient. For example, it may
take up to three months for transfused red cells to clear before a patient’s native red cells can be antigen typed.

In May 2014, one in vitro diagnostic (IVD) molecular test was approved by the Food and Drug Administration (FDA) and a second one is currently under review by FDA. Effective January 1, 2015, there will be Tier 2 codes available for blood group genotyping. However, it is difficult for hospitals to obtain adequate reimbursement for this important service with this CPT code status. Thus there remains a disincentive for hospitals and laboratories to provide this valuable testing for patients requiring transfusions.

AABB strongly supports the creation of a CPT Tier 1 code for this critical service. Such a code will improve reimbursement and ensure enhanced patient access to genotyping, especially for frequently transfused patients, and improved patient outcomes.

Thank you for your consideration of this important patient care issue. If you have any questions or require additional information, please contact AABB director of public policy, Theresa Wiegmann, JD at theresa_w@aabb.org or 301-215-6554.

Sincerely,

Miriam A. Markowitz
Chief Executive Officer