



Advancing Transfusion and  
Cellular Therapies Worldwide

**CMS HCPCS Public Meeting  
June 1, 2016  
Agenda Item # 13 – Bacterial Testing**

**Statement of AABB  
Presented by Theresa Wiegmann, JD, Director of Public Policy**

AABB (formerly known as the American Association of Blood Banks) believes there is a critical need for new HCPCS codes to cover the bacterially tested platelet products recently approved by the Food and Drug Administration. AABB is a non-profit standard-setting and professional organization representing virtually every blood center in the United States as well as hospital-based blood banks and transfusion services and professionals involved in all aspects of blood collection, processing and transfusion medicine.

AABB strongly supports the pending application for new HCPCS codes for bacterially tested platelet products. Hospitals need a means by which to be reimbursed for this important new safety advancement.

Bacterial contamination of platelets has been and continues to be a leading risk of transfusion therapy. Approximately 1 in 2,000 to 3,000 platelet transfusions are contaminated with bacteria, risking serious septic transfusion reactions leading to morbidity and mortality.

New technology recently approved by the Food and Drug Administration to test platelets for bacteria closer to the time of transfusion significantly reduces this risk, thus offering patients safer transfusions. In addition to improving the safety of platelet products, this particular bacterial testing importantly allows for extended shelf-life of platelets. Until this product was approved, platelets had to be transfused within five days of collection. Now, when tested with this technology, the shelf-life can be extended to seven days, thereby helping to prevent blood product shortages and achieve increased efficiency and minimization of waste of these critical biologics.

AABB, is concerned that without new codes to allow for appropriate billing of bacterially-tested platelets, patients will not have access to these products that offer increased safety and improved clinical outcomes. While the majority of blood products are transfused in the inpatient setting, an increasing amount of blood is provided in outpatient arenas. For example, one of the largest patient populations to receive platelet transfusions is oncology patients, many of whom are transfused in outpatient clinics.

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**Therefore, AABB strongly supports the applications being considered during this meeting for new HCPCS Level II codes for bacterially-tested platelet products.** We believe there is a clear national operating need for new codes for these products, which are clearly distinguishable from other blood components. Existing HCPCS Level II P codes for individual blood products were based on processing methods – such as leukocyte-reduction and irradiation. Bacterial testing is operationally and clinically different from other processing methods. There is a clear need for new codes to address this potentially life-saving technology.

In response to the pending application, CMS' preliminary decision is to establish a HCPCS modifier for "rapid bacterial tested" to be appended to existing platelet product codes. At first glance, AABB has some concerns about assigning a modifier, as opposed to individual HCPCS codes to these new platelet products. This is a notable departure from the current system of assigning a unique HCPCS code for each blood product. Therefore, there are questions about whether hospitals will receive adequate payment using the modifier approach and how these payments will be determined. Moreover, creating a new method for billing for one blood product, unlike the system used for all other products, adds complexity to an already complicated billing system, thereby potentially increasing the likelihood of errors. As a result, hospitals may underbill for this valuable product.

If CMS proceeds with adopting a modifier for bacterial testing, it must be accompanied with adequate payments. In addition, if the agency pursues this coding path, AABB recommends that it be closely evaluated to ensure that hospitals can implement this change in a way that does not undermine payments for blood products and transfusion services.

Without the ability to bill for and be reimbursed for bacterially-tested platelet products, financially-pressed hospitals may be reluctant to adopt this safety enhancement. Moreover, non-profit blood centers, which are already struggling in today's increasingly cost-restrained and competitive environment, lack the means to absorb additional costs associated with blood products. For this reason, it remains critical that there continue to be individual outpatient payments for unique blood products. Just as blood safety and availability is a national public health priority, as recognized by the Department of Health and Human Services, improving Medicare reimbursement for these life-saving products should be a priority at CMS.