July 26, 2006

Herb Kuhn
Director
Center for Medicare Management
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
CMM-Mailstop C5-01-14

Dear Mr. Kuhn:

I am writing to you on behalf of AABB to express our concerns about Medicare payments to hospitals for certain laboratory processing services associated with bone marrow and peripheral blood progenitor cell transplants. On behalf of our members, which include approximately 1,800 institutions, including hospital based laboratories, transfusion services and blood and bone marrow collection facilities, as well as approximately 8,000 individuals involved in blood, bone marrow and peripheral blood stem cell collection, processing, storage and infusion, AABB (formerly known as the American Association of Blood Banks) strongly believes that the Centers for Medicare and Medicaid Services (CMS) payments for such services need to be adjusted to reflect the actual costs of providing potentially life-saving care.

The specific CPT codes we are concerned about are 38207 through 38215 and 38204. **Codes 38207 through 38215** are for various cell-processing steps required before bone marrow/stem cells can be transplanted or reinfused in the patient. In 2001, in response to a request from a coalition of professional organizations, including AABB, the American Society of Hematology (ASH) and American Society for Blood and Marrow Transplantation (ASBMT), the Relative Value Update Committee (RUC) established interim work values for the physician oversight and quality review of the cell processing activities. However, CMS did not accept RUC’s recommendations.

These codes are not recognized under the physician fee schedule. AABB believes that it is appropriate that the services covered in these codes are not included in the clinical laboratory fee schedule; similarly, these services cannot be bundled easily into ambulatory payment classifications (APCs). Many of these services can be provided in three different settings: in hospitals, at blood centers or at free-standing exempt cancer centers. These services also fall under both part A and part B of Medicare. Collection procedures and some processing steps are typically performed in an outpatient or blood
center setting in advance of the infusion, and some processing (e.g., thawing) performed on the day of the infusion may be performed at an independent blood center or in the hospital. The bone marrow or stem cell infusion is performed in the inpatient setting.

CMS has established the following three “G” codes to be used in lieu of codes 38207-38215: G0265, G0266 and G0267, which are valued from only $11 to $32. AABB notes several significant problems associated with the G codes. First, these codes are not sufficiently descriptive of the services rendered. For example, code G0267 covers all of the various cell depletion activities (T-cells, platelets, red blood cells, etc.), which are described in codes 38210-38215. The costs hospitals incur in performing these procedures vary significantly and a single rate for cell depletion is not appropriate. AABB urges CMS to utilize the CPT codes for payment to the facility for these services. In addition, the payment levels for G0265 and G0266 ($14.11) under the Clinical Laboratory Fee Schedule are entirely inadequate to cover the actual costs associated with cryopreserving and thawing bone marrow or stem cells for transplant.

It should also be noted that G0265 and G0266 should not be valued under the laboratory fee schedule since they are not diagnostic laboratory tests. Rather, G0265 and G0266 refer to services associated with preparing bone marrow/stem cells for transplant that are analogous to blood banking cross matching and other blood processing codes. Such blood processing codes are excluded from the clinical laboratory fee schedule and are payable under the APC system. AABB would be pleased to work with CMS to determine the actual cost of providing these services, which include antibody flow cytometry testing (costing several hundred dollars) as well as the use of disposable supplies costing several hundred additional dollars.

Code G0267 has appropriately been excluded from the clinical laboratory fee schedule. However, the assigned payment of $216.73 for this service under APC 0110 is grossly inadequate. APC 0110 is for blood transfusion procedures. The costs of depleting T-cells, tumor cells, etc., from bone marrow/stem cells are not at all similar to the cost of a blood transfusion service. For example, T-cell depletion often involves the use of disposable supplies costing over $7,000. The Isolex 300 stem cell reagent kit alone costs almost $5,000 and 1.5 such kits are typically used in a procedure. These procedures typically require 4-10 hours of technical time to prepare the product for infusion.

**Code 38204** is defined as the management of a search for an unrelated bone marrow/stem cell donor for transplant. In 2001, the RUC agreed with AABB, ASH, ASBMT and others that the physician had a critical role in this service and assigned interim relative value units (RVUs) for the physician work associated with the procedures. However, CMS questioned the extent of physician involvement in this service and considered the service to be “bundled” into some other code. AABB does not understand with which code this service is considered “bundled.” The only code that it could be bundled with is 38240 (allogeneic infusion). However, this code has never been surveyed and still has its original value from the early 1990s. That value cannot be relevant today since, at that time, there had only been a very few unrelated transplants. In addition, it should be noted
that the physician who harvests or transplants the bone marrow is frequently not the same physician who manages the search for a donor.

AABB would appreciate the opportunity to meet with you and other interested parties to discuss possible strategies for addressing the above concerns to ensure that hospitals are fairly paid for these life-saving services. We will contact you shortly to schedule such a meeting. In the meantime, if you have any questions or require additional information, please contact AABB’s director of public policy, Theresa Wiegmann, JD, at 301-215-6554 or Theresa_L@aabb.org. Thank you for your attention to this important issue.

Sincerely,

Christopher D. Hillyer, MD
President

Cc: Terrence Kay, MD
    Kenneth Simon, MD