



Advancing Transfusion and
Cellular Therapies Worldwide

June 25, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates (CMS-1694-P)

Dear Administrator Verma:

AABB appreciates the opportunity to submit comments in response to the proposed rule announcing Medicare payment policies and rates for the hospital inpatient prospective payment system (IPPS) for fiscal year 2019 (Proposed Rule), which was published in the Federal Register on May 7, 2018.

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine, cellular therapies and patient blood management. The association is committed to “making transfusion medicine and cellular therapies safe, available and effective worldwide.” AABB works toward this vision by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers. AABB’s comments focus on payment policies related to allogeneic hematopoietic cell transplant (HCT) and chimeric antigen receptor (CAR) T-cell therapies.

AABB encourages the Centers for Medicare & Medicaid Services (CMS) to adopt policies that improve coding for inpatient HCT claims.

AABB believes that CMS should consider several coding changes for inpatient HCT. In the CY 2017 hospital outpatient prospective payment system (OPPS) final rule, CMS established revenue code 0815 (Allogeneic Stem Cell Acquisition/Donor Services) to capture the costs of donor search and cell acquisition activities for allogeneic HCT and indicated that all claims in C-

4550 Montgomery Avenue
Suite 700, North Tower
Bethesda, MD 20814-3304
+ 1 301.215.6492
+ 1 301.657.0957 – FAX
www.aabb.org

APC 5244 (Level 4 Blood Product Exchange and Related Services) with CPT code 38240 (Hematopoietic progenitor cells; allogeneic transplantation per donor) will require revenue code 0815. Similarly, AABB believes that CMS should require revenue code 0815 to be utilized on inpatient allogeneic transplant claims assigned to MS-DRG 014 (Allogeneic Bone Marrow Transplant) so that the revenue code captures all costs of donor search and acquisition activities for allogeneic HCT, regardless of a patient's setting of care. In addition, we request that CMS require all claims under MS-DRG 014 to have a donor source code present, since this information is essential to understanding differences between related donors and unrelated donors. We also encourage CMS to ensure that autologous ICD-10-PSC codes are assigned to the autologous transplant MS-DRGs (MS-DRG 016 (Autologous Bone Marrow Transplant w/ CC/MCC) and MS-DRG 017 (Autologous Bone Marrow Transplant w/o CC/MCC)), and not to MS-DRG 014. Finally, we encourage CMS to issue instructions on how hospitals should aggregate donor search and cell acquisition costs to cost center 77 (Allogeneic Stem Cell Acquisition), which is intended to capture such costs.

AABB encourages CMS to adopt coverage and reimbursement policies for CAR-T cell therapies that support patients' access to these novel, life-savings treatments.

AABB commends CMS for exploring several alternative payment policies for CAR-T cell therapies. AABB values that the Food and Drug Administration (FDA) recently approved two CAR-T cell therapies, Kymriah and Yescarta, and recognizes that other cellular therapies, including additional CAR-T products, are in development. We appreciate the clinical significance of these new therapies, as well as the challenges they present related to reimbursement. We recognize that CMS' coverage and payment policies related to Kymriah and Yescarta will establish precedent for new life-saving therapies.

We believe it is imperative for CMS to ensure that Medicare coverage and reimbursement policies for CAR-T cell therapies do not interfere with beneficiaries' access to these life-saving therapies. We urge CMS to establish flexible coverage policies that permit physicians to use the best product for each individual patient in the most appropriate setting of care. Similarly, we encourage CMS to ensure that beneficiaries have access to CAR-T cell therapies by establishing payment policies that: (1) have a site-neutral, product-agnostic payment structure; (2) cover the cost of the therapy as well as all associated care services; (3) minimize financial losses for CAR-T cell therapies; and (4) create flexibility for future products and combination therapies. We urge CMS to avoid establishing or adopting policies that have the potential to disrupt or impact the rate-setting process and reimbursement for other cellular therapies, including HCTs.

AABB recognizes the complexity of establishing new payment policies for CAR-T cell therapies. We encourage CMS to establish transparent, predictable reimbursement policies that result in appropriate payment rates and ensure Medicare beneficiaries' access to these novel treatments.

* * * *

If you have any questions or need additional information, please contact Leah Stone, Director, Public Policy & Advocacy at 301-215-6554 or lmstone@aabb.org.

Sincerely,

Mary Beth Bassett
President
AABB