



Advancing Transfusion and
Cellular Therapies Worldwide

June 24, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1716-P)

Dear Administrator Verma:

AABB appreciates the opportunity to submit comments in response to the proposed rule announcing updates to hospital inpatient payment policies for FY 2020 (Proposed Rule). AABB's comments focus on CMS' proposals related to payment policies for CAR T-cell therapies as well as reimbursement for bone marrow and cord blood transplant.

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. 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 individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

AABB supports the comments submitted by NMDP/Be the Match, the American Society for Transplantation and Cellular Therapy (ASTCT, formerly known as the American Society for Blood and Marrow Transplantation) and the American Society of Hematology (ASH) and their

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recommendations related to payment for CAR T-cell therapies as well as policies related to reimbursement for bone marrow and cord blood transplant.

In addition, AABB urges CMS to ensure that any policy supports coverage and reimbursement for all items and services required throughout a CAR T and related immune effector cell therapy treatment protocol. As CMS recognized in the “Proposed Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers,” CAR T-cell treatment protocols involve several essential steps, which the Agency summarized as: (1) lymphocyte harvesting from the patient with cancer; (2) creation of cancer-targeting lymphocytes in vitro using various immune modulators; (3) selection of lymphocytes with reactivity to cancer antigens using enzymelinked immune-assay; (4) depletion of the patient's remaining lymphocytes using immunosuppressive agents; and (5) transfusion of the cancer-targeting lymphocytes back into the patient with cancer-this transfusion represents one treatment.

Thus, CMS acknowledges that CAR T-cell therapies involve separate and distinct processes outside of the in vitro cell manipulations. Importantly, each of these steps are labor intensive, requiring the expertise of physicians and other health care professionals, oversight and monitoring. In addition to these steps, monitoring for and treatment of therapy related complications, such as cytokine release syndrome and neurotoxicity, are important aspects of CAR T-cell therapy protocols. We urge CMS to recognize that appropriate coverage and reimbursement is necessary to cover all items and services furnished throughout the continuum of CAR T and related immune effector cell therapy treatments.

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

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB