



April 22, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G 200
Independence Avenue, SW
Washington, DC 20201

Re: Reimbursement for Chimeric Antigen Receptor (CAR) T-cell Therapy

Dear Administrator Verma:

On behalf of the Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 230 institutions across the health care spectrum, I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to ensure continued patient access to chimeric antigen receptor (CAR) T-cell therapy by establishing an adequate, permanent Medicare reimbursement solution in fiscal year 2021.

PMC defines personalized medicine as an evolving field that uses diagnostic tools to identify specific biological markers to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history, circumstances, and values, personalized medicine allows doctors and patients to develop targeted treatment or prevention plans.

Personalized medicine is helping to shift the patient and provider experience away from trial-and-error toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

CAR T-cell therapy represents a significant advancement in personalized medicine. Some cancer patients with very poor prognoses have experienced life-improving and life-extending outcomes resulting from CAR T-cell therapy. The CAR T-cell therapies already on the market have had a profound impact on the lives of patients for whom they are intended to treat and the promise of new CAR T-cell therapies provides hope for many patients with other types of cancers.

CMS has recognized the clinical value of CAR T-cell therapy by issuing a National Coverage Determination in 2019 and by making incremental changes to reimbursement through the hospital

BOARD OF DIRECTORS

President
Edward Abrahams, Ph.D.

Chair
Jay G. Wohlgemuth, M.D.
Quest Diagnostics

Vice Chair
William S. Dalton, Ph.D., M.D.
M2Gen

Treasurer
Mark P. Stevenson, M.B.A.
Thermo Fisher Scientific

Secretary
Michael Pellini, M.D., M.B.A.
Section 32

Bonnie J. Addario
GO₂ Foundation for Lung Cancer

Antoni Andreu, M.D., Ph.D.
EATRIS

Randy Burkholder
PhRMA

Stephen L. Eck, M.D., Ph.D.
Immatics US

Lori Frank, Ph.D.
Alzheimer's Foundation of America

Brad Gray
NanoString Technologies

Kris Joshi, Ph.D.
Change Healthcare

Anne-Marie Martin, Ph.D.
Novartis

Howard McLeod, Pharm.D.

J. Brian Munroe
Bausch Health Companies

Lincoln Nadauld, M.D., Ph.D.
Intermountain Healthcare

Kimberly J. Popovits

Hakan Sakul, Ph.D.
Pfizer, Inc.

Michael S. Sherman, M.D., M.B.A.
Harvard Pilgrim Health Care

Apostolia Tsimberidou, M.D., Ph.D.
M.D. Anderson Cancer Center

Michael Vasconcelles, M.D.
Flatiron Health

Werner Verbiest
Johnson & Johnson

inpatient prospective payment system. The agency should be commended for taking these steps, including the decision to grant new technology add-on payments (NTAP) for the CAR T-cell therapies currently approved by the U.S. Food and Drug Administration.

We are aware that CMS' NTAPs associated with these CAR T-cell therapies will expire on September 30, 2020. Hospitals will face a reimbursement cliff if CMS does not act to create a permanent payment solution by fiscal year 2021. The resulting reimbursement gap would leave providers with larger deficits due to the additional costs of care associated with furnishing CAR T-cell therapy, and likely further compromise patient access.

Patients will only have access to exciting advances like CAR T-cell therapy if reimbursement policies align with the costs of caring for patients in need of treatment. To ensure beneficiaries can continue receiving CAR T-cell therapy after the existing NTAPs expire, PMC urges CMS to implement a permanent reimbursement solution, such as a new Medicare Severity-Diagnosis Related Group (MS-DRG) for fiscal year 2021. We believe a permanent solution can be formulated in a manner that reflects the true expenses associated with the administration of the therapy outside of the context of a clinical trial.

PMC appreciates your commitment to ensuring that beneficiaries have access to transformational therapies. We look forward to working with you and your colleagues at CMS to protect patient access to CAR T-cell therapy and to continue fostering innovation in this therapeutic area. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,



Cynthia A. Bens
Senior Vice President, Public Policy