PERSONALIZED MEDICINE COALITION

July 10, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1735P)

Dear Administrator Verma:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 230 institutions across the health care spectrum, appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS)' *Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule for FY 2021.* PMC supports the establishment of a new Medicare Severity-Diagnosis Related Group (MS-DRG) for chimeric antigen receptor (CAR) T-cell therapies and commends CMS for its efforts to ensure appropriate payment for CAR T-cell therapies through proposed updates for FY 2021. While we recognize there are numerous important payment issues addressed in the proposed rule, PMC's comments are confined to the impact of specific proposed payment changes on beneficiary access to CAR T-cell therapies and similar therapies that are forthcoming.

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.

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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. The promise of new CAR T-cell therapies, meanwhile, provides hope for many patients with other types of cancers.

Statement of Neutrality

Many of PMC's members will present their own responses to CMS and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the Medicare *IPPS Proposed Rule* for FY 2021.

Considerations for CMS in Finalizing Proposed Rule

The *IPPS Proposed Rule* for FY 2021 signals a continued willingness at the agency to adapt the current payment structure to account for innovative treatments and proposes payment updates to the current inpatient payment structure that would continue access to CAR T-cell therapies.

The proposed rule specifically calls for terminating the expiring New Technology Add-on Payments (NTAPs) for two CAR T-cell products currently approved by the U.S. Food and Drug Administration (FDA) and transferring them to a newly created MS-DRG 018 with a base payment for Fiscal Year 2021. In setting this payment rate, CMS further proposes not to use claims data generated from patients in clinical trials and recognizes the limited data set available. We believe these changes are responsive to PMC's previous requests for a permanent reimbursement solution for CAR T-cell therapy that is formulated in a manner that better reflects the true expenses associated with patient care. For this reason, PMC urges CMS to finalize its proposal to create MS-DRG 018. We also request CMS continue to evaluate if current reimbursement levels are adequate to ensure access to CAR T -cell therapies for Medicare patients and consider opportunities to further refine the payment formula for CAR T-cell therapies in future rule-making.

PMC is pleased with the direction of the proposed rule but also recognizes the importance of ensuring that these policy changes extend to new CAR T-cell therapies as they secure FDA approval. There is a robust pipeline of new CAR T-cell therapies that will come to market in the near future. PMC urges CMS to immediately assign these new CAR T-cell therapies to MS-DRG 018 upon FDA approval. We believe that doing so will yield significant benefits for patients by accelerating access to these potentially life-saving treatments and adequately reimbursing providers for their patient cases.

PMC also asks CMS to recognize that the portfolio of T-cell immunotherapy is expanding to include other types of cell therapies, such as tumor infiltrating lymphocytes (TIL) and genetically-engineered T-cell receptor (TCR) technologies. As these types of T-cell immunotherapies enter the market, it will be critical that providers are appropriately reimbursed for these and other transformative therapies. PMC looks forward to working with CMS in the near future on ways to support robust patient access to other

T-cell immunotherapies and transformative therapies by applying the learnings from CAR T-cell therapy reimbursement.

Finally, PMC asks CMS to consider that new cell therapies in the research and development pipeline have important differences. As cell therapy applications are submitted to the agency for NTAP status, factors such as the uniqueness of patient populations, disease areas treated, specific antigen targets and other differences in the therapies themselves should be acknowledged. Such recognition may allow them to meet the newness criterion needed to receive NTAP approval in future years and remove a potential barrier to access for innovative treatments.

PMC appreciates your commitment to ensuring that beneficiaries have access to transformative 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