PERSONALIZED MEDICINE COALITION

June 28, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1752-P
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 2022 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals (CMS 2021-0070-0002)

Dear Administrator Brooks-LaSure:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 220 institutions across the health care spectrum, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on the *Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule for FY 2022*[i]. As you may know, in 2020, PMC supported the establishment of a new Medicare Severity-Diagnosis Related Group (MS-DRG) for chimeric antigen receptor (CAR) T-cell therapies as a way to accelerate access to these potentially life-saving personalized treatments.[ii] We believe the thoughtful continuation of MS-DRG 018 will yield significant benefits for patients, providers, and hospitals. While PMC recognizes there are numerous important payment issues addressed in the proposed rule, our comments are limited 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 in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences 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 with certain forms of lymphoma, leukemia, and multiple myeloma. The promise of new CAR T-cell therapies, meanwhile, provides hope for many patients with other hard-to-treat cancers.

Statement of Neutrality

Many of PMC's members will present their own responses to the *Medicare IPPS Proposed Rule for FY 2022* 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 rule.

Considerations for CMS in Finalizing Proposed Rule

The *IPPS Proposed Rule for FY 2022* specifically calls for continued use of the newly established Medicare MS-DRG for CAR T-cell treatment stays. The rule provides for differential reimbursement based on whether the treatment was provided as part of a clinical trial. It also accounts for the impact of the COVID-19 pandemic on patient cases. These proposals demonstrate a continued willingness at the agency to adapt the current payment structure to account for innovative treatments and propose updates to the current inpatient payment structure that would maintain access to CAR T-cell therapies.

CMS stated in the *IPPS FY 2021 Final Rule* that clinical trial cases for CAR T-cell treatment typically cost 17 percent of what non-clinical trial cases cost because they do not incur drug costs. For this reason, the agency applied an adjustment factor of 0.17 to the relative weight of MS-DRG 018 when reimbursing for clinical trial cases.[iii] PMC supported this adjustment and thinks that it is reasonable to continue in FY 2022. CMS also proposes using 2019 Medicare Provider Analysis and Review data to set relative weights for MS-DRGs in FY 2022. This proposed change in methodology is due to the COVID-19 pandemic's impact on utilization during 2020, which may distort cost estimates. We believe this proposal is also 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.[iv]

PMC also appreciates that CMS noted from previous stakeholder comments that the portfolio of T-cell immunotherapy is expanding to include other types of transformative cell therapies for which providers will need adequate reimbursement. In response, CMS proposes renaming MS-DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" in FY 2022 to account for other immunotherapies. While we share the agency's interest in the development of a sustainable payment mechanism, we are concerned that the inclusion of additional immunotherapies that could be mapped to MS-DRG 018 may lead to more heterogeneous cases being considered when setting reimbursement and

may lead to reductions in the base rate over time. This could result in uniform reimbursement for cases that differ significantly in resource costs. We urge CMS to consider additional analysis before expanding the MS-DRG 018 to include "other immunotherapies." We believe that a thoughtful analysis of the therapeutic landscape conducted with input from multiple stakeholders will better support robust patient access to CAR T-cell and other transformative therapies in the future.

Finally, in our comments on the *FY 2021 IPPS Proposed Rule*, PMC asked CMS to consider that new cell therapies in the research and development pipeline have important differences such as the uniqueness of patient populations, disease areas treated, specific antigen targets and other differences in the therapies themselves that should qualify them to receive New Technology Add-on Payment (NTAP) status. There are currently no CAR-T therapies with NTAP status, however we understand that four applications for NTAPs are included in the FY 2022 proposed rule. We encourage CMS to assign NTAPs for new CAR-T therapies that meet the required criteria, including the applications under consideration for lisocabtagene maraleucel, ciltacabtagene autoleucel (cilta-cel), idecabtagene vicleucel, and lifileucel, to 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

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[i] Centers for Medicare and Medicaid Services. *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 2022 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals (CMS 2021-0070-0002)*. May 10, 2021. https://www.regulations.gov/document/CMS-2021-0070-0002.

[ii] Personalized Medicine Coalition. *Comment Letter on Centers for Medicare and Medicaid Services 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*. July 10, 2020. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_CAR-T_MS-DRG_7.10.20.pdf.

[iii] Centers for Medicare and Medicaid Services. *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Final 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-2020-0052-0860)*. September 18, 2020. https://www.regulations.gov/document/CMS-2020-0052-0860.

[iv] Personalized Medicine Coalition. *Letter to Administrator Verma on Reimbursement for Chimeric Antigen Receptor (CAR) T-cell Therapy*. April 22, 2020. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_on_CMS_Reimbursement_Policy_for_CAR_T-cell_Therapy_April_2020.pdf.