



June 17, 2022

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; Fiscal Year 2023 Hospital Inpatient Prospective Payment Systems; Quality Programs and Medicare Promoting Interoperability Program Requirements, etc. (CMS-2022-0074-0006)

Dear Administrator Brooks-LaSure:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 220 institutions from 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 2023*.ⁱ As you may recall, in its comment letter on CMS' *IPPS Proposed Rule for FY 2021*, 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 as outlined in CMS' proposed rule for FY 2023 will continue to yield significant benefits for patients, providers, and hospitals, and we applaud CMS for taking this approach. While PMC recognizes there are numerous important payment issues addressed in the *IPPS Proposed Rule for FY 2023*, our comments are limited to the impact of specific proposed policy changes on beneficiary access to CAR T-cell therapies and similar therapies that are forthcoming for cancer and other diseases.

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

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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. In February of this year, Dr. Carl June, the University of Pennsylvania immunologist who designed the first CAR T-cell treatment, stated that “We can now conclude that CAR T-cells can actually cure patients,” based on evidence that CAR T-cells are still active in patients a decade after treatment and at least two patients remain free of cancer.ⁱⁱⁱ Results like these and the promise of future cell and gene therapies provide hope for many patients with cancer and other hard-to-treat diseases.

Statement of Neutrality

Many of PMC’s members will present their own responses to the *Medicare IPPS Proposed Rule for FY 2023* 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 proposed rule.

Considerations for CMS in Finalizing Proposed Rule

PMC appreciates that CMS’ *IPPS Proposed Rule for FY 2023* maintains the policies adopted for MS-DRG 018 in FY 2021 and FY 2022, which is a significant step toward greater patient access to CAR T-cell therapy. We believe the FY 2023 proposal is responsive to PMC’s previous requests for a permanent reimbursement solution for CAR T-cell therapy that is formulated in a manner that reflects the true expenses associated with patient care.^{iv} The FY 2023 proposed rule provides a base payment rate that is the highest of the MS-DRGs now in place, it allows for differential reimbursement based on whether treatment was provided as part of a clinical trial, it accounts for the impact of the COVID-19 pandemic on CAR T-cell patient cases, and it would institute a permanent 10 percent cap on any reductions to the MS-DRG base payment adjustment. These proposals all demonstrate a continued willingness at the agency to maintain access to CAR T-cell therapies. Each should be supported.

In our comments on the FY 2021 and FY 2022 IPPS proposed rules, PMC asked CMS to consider that new CAR T-cell therapies in the research and development pipeline differ from the CAR T-cell treatments now available, with differences relating to the uniqueness of patient populations, disease areas treated, specific antigen targets, and other differences in the therapies themselves. PMC suggested that these differences should qualify forthcoming CAR T-cell therapies to receive New Technology Add-on Payment (NTAP) statuses. In FY 2023, we urge CMS to assign NTAP status for new CAR T-cell therapies that meet the required criteria, including requests under consideration for CARVYKTI

and lifileucel. NTAPs encourage hospitals to adopt breakthrough technologies by helping them recover some of the increased costs associated with offering innovative treatments to patients. Granting NTAP status is another way CMS can remove a potential barrier to CAR-T cell therapy access.

The *IPPS Proposed Rule for FY 2023* calls for the continued use of the MS-DRG 018 established for CAR T-cell treatment and CMS' FY 2022 policy that expanded MS-DRG 018 to include certain other immunotherapies. While we share the agency's interest in developing a sustainable mechanism to accommodate the expanding portfolio of other types of transformative therapies for which providers will need adequate reimbursement, we remain concerned that the inclusion of additional procedure codes associated with other therapies will lead to reductions in the base rate for MS-DRG 018 over time.^v We encourage CMS to clarify its methodology for the inclusion of new procedure codes within MS-DRG 018. We also ask CMS to continue assessing the appropriateness of therapies assigned to MS-DRG 018 so that the cost and resource needs of potential new additions to MS-DRG 018 do not harm access to current therapies.

Finally, we believe that a thoughtful analysis of the therapeutic landscape conducted with input from multiple stakeholders will best support robust patient access to CAR T-cell and other transformative cell and gene therapies in the future. In fact, the co-chairs of the Congressional Personalized Medicine Caucus,^{vi} in partnership with PMC, convened a recent briefing for policymakers about some of the educational, reimbursement, and clinical adoption challenges that make it difficult for clinicians to take full advantage of emerging opportunities to tailor health care for each patient. The briefing highlighted the urgent need for solutions designed to ensure that forthcoming cell and gene therapies for cancer and rare diseases are accessible to patients who need them as soon as they come to market.^{vii} We appreciate that CMS intends to convene town hall meetings on reimbursement for cell and gene therapies to explore creative policy solutions. PMC also applauds the agency for including a request for information in the FY 2023 proposed rule calling attention to the special challenges of reimbursement adequacy often faced for rare disease treatment under the IPPS. We hope these are initial steps toward meaningful changes that reduce IPPS payment disparities for treatment of rare disease patients.

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 and related therapeutic areas for patients with unmet needs. 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

ⁱ Centers for Medicare & Medicaid Services. *Medicare Program; Fiscal Year 2023 Hospital Inpatient Prospective Payment Systems; Quality Programs and Medicare Promoting Interoperability Program Requirements, etc.* (CMS-2022-0074-0006). May 10, 2022. <https://www.regulations.gov/document/CMS-2022-0074-0006>.

ⁱⁱ Personalized Medicine Coalition. *Comment Letter on Centers for Medicare & 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 *Endpoints*. “Carl June: ‘We can now conclude that CAR-T cells can actually cure patients.’” February 2, 2022. <https://endpts.com/carl-june-we-can-now-conclude-that-car-t-cells-can-actually-cure-patients/>.

^{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.

^v Personalized Medicine Coalition. *Comment Letter on Centers for Medicare & 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.* June 28, 2021. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Comments_CAR-T_MS-DRG_IPPS_FY_2022.pdf.

^{vi} *Congressional Personalized Medicine Caucus: Origins and Purpose.* Accessed June 15, 2022. https://www.personalizedmedicinecoalition.org/Congressional_Caucus/OriginsPurpose.

^{vii} Personalized Medicine Coalition. *Promoting Innovation and Delivery of Cell and Gene Therapies.* April 28, 2022. <https://www.youtube.com/watch?v=-H4t8P1ZqZc>.