PERSONALIZED MEDICINE COALITION

September 9, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1809-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; etc (CMS-1809-P)

Dear Administrator Brooks-LaSure:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on payment policies under the CY 2025 Outpatient Prospective Payment System (OPPS) proposed rule.[i] While PMC recognizes that there are numerous important payment issues addressed in the OPPS proposed rule for CY 2025, our comments are focused on the impact of specific proposed policy changes on beneficiary access to chimeric antigen receptor (CAR) T-cell therapies and forthcoming transformative personalized medicine technologies. We support the exclusion of CAR T-cell therapy from being packaged in any comprehensive Ambulatory Payment Classification Group (C-APC) that CMS uses to establish reimbursement levels for certain treatments and their associated administration costs. In addition, we support CMS' proposal to unbundle payment for certain diagnostic radiopharmaceuticals products, which will help beneficiaries access targeted diagnostic radiopharmaceuticals. We also encourage CMS to consider the potential impact of adopting a proposed blended payment rate on reimbursement for promising medical technologies provided in clinical trials under the Coverage with Evidence Development (CED) program.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests and individual details about a person's health 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

and its members are leading the way in personalized medicine and in developing evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Statement of Neutrality

Many of PMC's members will present their own responses to the Medicare CY 2025 OPPS proposed rule 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 adversely impact the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed rule.

Consideration for CMS in Finalizing the Proposed Rule

Exclusion of CAR T-cell Therapies and Other Cell and Gene Therapies From C-APC Packaging

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. With CAR T-cell therapies being tested in hundreds of clinical trials, the promise of other cell and gene therapies provides hope for many patients with cancer and other hard-to-treat diseases.

Since CAR T-cell therapies became available in the inpatient setting, PMC has supported CMS' efforts to facilitate access to CAR T-cell therapies through its Inpatient Prospective Payment System, or IPPS, by establishing a permanent reimbursement solution that is formulated in a manner reflecting the true expenses associated with patient care.[ii] Although the administration of most CAR T-cell therapies has occurred in the inpatient setting, advancements in treatment protocols and improvements in patient management are making outpatient administration increasingly feasible.[iii] We understand that when delivered in the outpatient setting, these therapies are subject to Medicare reimbursement under CMS' OPPS, through which drugs and biologics are usually separately paid at average sales price (ASP) + 6 percent.

Facilitating the uptake of CAR T-cell therapy in the outpatient setting has the potential to significantly increase patients' access to these lifesaving treatments. Because CAR T-cell therapies are still predominantly delivered in the inpatient setting, their administration is constrained by treatment slots and demands for inpatient resources at authorized treatment centers. Distance to these centers is associated with older adults, African Americans, and patients with limited income being less likely to receive CAR T-cell therapy treatment.[iv] The limited number of treatment center locations further exacerbates access disparities, with many patients having to travel long distances and incurring additional expenses to receive treatment. As clinical criteria for selecting appropriate candidates for outpatient treatment are refined and supportive care measures evolve, the trend toward outpatient CAR T-cell therapy administration is likely to expand, presenting an important solution to ongoing patient access challenges for CAR T-cell therapies in the inpatient setting.

Increased outpatient utilization can reduce health care costs; decrease the burden on hospital resources before, during, and following treatment; increase the number of treatment centers administering CAR T-

cell therapies; and improve the convenience of treatment for patients. In fact, one study showed post-infusion costs were lower for patients who received CAR T-cell treatment in an outpatient setting versus an inpatient setting.[v] **Adequate and predictable Medicare reimbursement for CAR T-cell therapies in the hospital outpatient department setting – based on separate payment under CMS' ASP + 6 percent model – supports more widespread and equitable access to CAR T-cell therapy, especially for patients in rural or underserved communities who may have limited access to specialized inpatient facilities.**

Under the OPPS, reimbursement levels for treatments and their associated administration costs can be bundled under a comprehensive Ambulatory Payment Classification Group, or C-APC. C-APCs were originally established to simplify billing for routine outpatient services with predictable costs. However, packaging CAR T-cell therapy in a C-APC may result in reduced reimbursement for hospital outpatient departments. At a time when patient access to CAR T-cell treatment is limited and outpatient administration offers a promising pathway toward increasing beneficiary access, we believe packaging may disincentivize outpatient administration and, thus, adversely impact expanded patient access to these transformative therapies in community settings. Discouraging smaller, financially strained outpatient departments from offering CAR T-cell treatments would disproportionately impact rural and underserved communities and undermine CMS' efforts to promote health equity. **Therefore, PMC supports CMS' proposal to exclude certain qualifying cell and gene therapies, including CAR T-cell therapies, from C-APC packaging for one year in CY 2025.**

In addition, we urge CMS against creating a new C-APC packaging reimbursement for CAR T-cell therapies and their associated administration services. Packaging CAR T-cell therapy into a C-APC would pay all therapies the same, regardless of the cost to a hospital of a specific product. Compared to separate payment at ASP + 6 percent, packaging may result in inadequate reimbursement and material losses for hospital outpatient departments. Such distorted payment will disincentivize outpatient administration and incentivize providers to make treatment choices based on reimbursement rather than clinical appropriateness, which would have unintended consequences for patient access.

Unbundling Reimbursement for Diagnostic Radiopharmaceutical Products

CMS currently bundles payment for diagnostic radiopharmaceuticals with payment for their associated diagnostic test or procedure. This payment policy can undermine access when hospitals decline to offer certain services due to inadequate reimbursement from the bundled payment methodology, such as diagnostic radiopharmaceuticals with a higher cost but lower utilization. **Therefore, PMC supports CMS' proposal to unbundle payment for certain diagnostic radiopharmaceutical products, and we encourage the agency to finalize the proposed separate payment policy for CY 2025.**

Amending this payment policy will ensure that patients can access advanced imaging for a number of serious health conditions, including Alzheimer's disease, certain cancers, Parkinson's disease, and cardiovascular disease, in the hospital outpatient department setting. This payment change is especially important for patient access to targeted diagnostic radiopharmaceuticals, also known as precision diagnostic radiopharmaceuticals, that are crucial to ensuring that Medicare beneficiaries receive the most effective and efficient treatments.

Beta amyloid positron emission tomography (PET) imaging, for example, is a critical tool for diagnosing Alzheimer's disease (AD), ruling out a diagnosis of AD, and evaluating whether and how

certain treatments may work for a patient. Abnormal levels of amyloid in the brain are one of the key pathologies found in patients with AD, and beta amyloid PET imaging is an essential tool for physicians in detecting the presence and level of amyloid plaques. Knowing amyloid status adds clarity for physicians managing the treatment of patients with suspected Alzheimer's disease by helping them reduce adverse events from inappropriate treatment, thus improving the chances of directing appropriate care. The emergence of new anti-amyloid treatments, some requiring multiple PET scans to inform an individual patient's treatment course, makes timely and appropriate access to this imaging tool essential for individuals living with AD and their families.

In the United States, approximately 50 percent of PET imaging capacity is in the hospital outpatient department setting, where it can be easier for certain beneficiaries – such as patients living in rural areas – to access beta amyloid PET scans. PMC previously supported CMS' efforts to remove national coverage restrictions limiting access to beta amyloid PET imaging in AD.[vi] In the CY25 OPPS proposed rule, we applaud CMS for acknowledging and proposing to address access concerns created by its current payment methodology for diagnostic radiopharmaceuticals delivered in the outpatient setting at safety net hospitals and within underserved communities. Unbundling payment will help ensure that patients with AD and other diseases have more equitable access to the precision diagnostic and imaging tools needed to address their medical needs.

Blended Payment Rate for Products Covered Under CED Clinical Trials

For certain drugs and devices being studied in clinical trials under a Coverage with Evidence Development (CED) National Coverage Determination (NCD), CMS is proposing to adopt a new blended payment rate to preserve study blinding. The proposed blended payment rate would include routine care costs and account for the frequency of the product being studied versus the control. If operationalized, we are concerned that CMS' blended payment proposal could potentially lead to overall lower reimbursement for certain products, including drugs and biologicals that have already received U.S. Food and Drug Administration approval. **PMC encourages CMS to consider the potential impact of adopting the proposed blended payment rate on lowering reimbursement for products covered under CED clinical trials and not finalize this proposed policy.**

CMS uses CED to cover promising technologies with a limited evidence base on the condition that they are furnished to Medicare beneficiaries in a setting of approved clinical studies or ongoing data collection. CED has been criticized for creating barriers that prevent wider access to medical breakthroughs, for limiting data for research, and, ultimately, for hampering innovation.[vii] In previous comments to CMS, PMC has expressed concerns with proposals that would further expand the applicability of CED to drugs and biologicals where existing Medicare coverage policy has been effective in ensuring Medicare beneficiaries have access to innovative personalized medicines.[viii] **In keeping with CMS' previously stated intentions to use CED to generally expand access to medical technologies, we continue to urge CMS to refrain from expanding the scope of CED for drugs and biologicals, which could adversely impact patient access to personalized medicine where the path to coverage and reimbursement may already be smooth and well-understood.**

Conclusion

Thank you for your commitment to ensuring that beneficiaries have access to transformative treatments and technologies like CAR T-cell therapies and targeted diagnostic radiopharmaceuticals in the

outpatient setting. We look forward to working with you and your colleagues at CMS to facilitate patient access to these and other advances in personalized medicine. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org or David Davenport, PMC's Manager of Public and Science Policy, at ddavenport@personalizedmedicinecoalition.org or 804-291-8572.

Sincerely yours,

Cynthia A. Bens
Senior Vice President, Public Policy

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[i] Centers for Medicare & Medicaid Services. *Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; etc (CMS-1809-P).* https://www.federalregister.gov/d/2024-15087. (Accessed September 3, 2024.)

[ii] Personalized Medicine Coalition. *Comment Letter on Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates, etc (CMS-1808-P).* June 10, 2024. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/06/comment-letter.pdf. (Accessed September 3, 2024.)

[iii] May, Brandon. "Hospital-Based Outpatient Approach to CAR T Therapy Is Safe, Feasible in Lymphoma and Multiple Myeloma." ASCO Annual Meeting 2023. *ASCO Daily News*. May 25, 2023. https://dailynews.ascopubs.org/do/hospital-based-outpatient-approach-car-t-therapy-safe-feasible-lymphoma-and-multiple. (Accessed September 3, 2024.)

[iv] Ahmed, Nausheen, et al. "Chimeric Antigen Receptor T-Cell Access in Patients with Relapsed/Refractory Large B-Cell Lymphoma: Association of Access with Social Determinants of Health and Travel Time to Treatment Centers." *Transplantation and Cellular Therapy*. July 2024. Vol. 30(7):714-725. https://doi.org/10.1016/j.jtct.2024.04.017. (Accessed September 3, 2024.)

[v] Hansen, Doris K, et al. "The Impact of Outpatient versus Inpatient Administration of CAR-T Therapies on Clinical, Economic, and Humanistic Outcomes in Patients with Hematological Cancer: A Systematic Literature Review." *Cancers (Basel).* December 7, 2023. Vol.15(24):5746. https://www.mdpi.com/2591950. (Accessed September 3, 2024.)

[vi] Personalized Medicine Coalition. *Comment Letter on Proposed National Coverage Determination Reconsideration for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431R).* August 16, 2023. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2023/08/comment-letter-1.pdf. (Accessed September 3, 2024.)

[vii] Grogan, Joe. "Medicare's 'Coverage With Evidence Development:' A Barrier To Patient Access And Innovation." *Health Affairs Forefront*. May 1, 2023. https://www.healthaffairs.org/content/forefront/medicare-s-coverage-evidence-development-policy-barrier-patient-access-and-innovation. (Accessed September 3, 2024.)

[viii] Personalized Medicine Coalition. *Comment Letter on Medicare Program; Transitional Coverage for Emerging Technologies (CMS-3421-NC) and Coverage with Evidence Development Proposed Guidance Document.* August 28, 2023. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2023/08/comment-letter-3.pdf. (Accessed September 3, 2024.)