June 9, 2026

Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare 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 2027 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1849-P)

Dear Administrator Oz:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group established 20 years ago and comprising more than 160 institutions from across the health care spectrum to promote the understanding and adoption of personalized medicine concepts, services, and products, 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 2027.[i] While PMC recognizes that there are numerous important payment issues addressed in the IPPS Proposed Rule for FY 2027, our comments are limited to the impact of specific proposed policy changes on beneficiary access to cell and gene therapies and other transformative personalized medicine technologies forthcoming in cancer, rare, and other diseases.

In our 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 2027 will yield significant benefits for patients, providers, and hospitals. PMC is concerned, however, with approaches proposed for New Technology Add-On Payment (NTAP) applications for therapies in FY 2027 and to the NTAP for breakthrough devices that may reduce patient access to new and innovative medical technologies.

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 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.

CAR T-cell therapy represents a significant advancement in personalized medicine. Some 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. Dr. Carl June, the University of Pennsylvania immunologist who designed the first CAR T-cell treatment, has 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 the fact that at least two of the first-ever patients treated with CAR T-cell therapies remain free of cancer.[iii] With cell and gene therapies being tested in hundreds of clinical trials, results like these provide hope for many patients with cancer and other hard-to-treat diseases including sickle cell disease, idiopathic macular telangiectasia type 2 (MacTel), recessive dystrophic epidermolysis bullosa (RDEB), spinal muscular atrophy (SMA), and Wiskott-Aldrich syndrome (WAS).

Statement of Neutrality

Many of PMC's members will present their own responses to the Medicare IPPS Proposed Rule for FY 2027 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 CAR T-Cell Therapies Under MS-DRG 018

PMC appreciates that CMS' IPPS Proposed Rule for FY 2027 takes a similar overall approach to policies adopted for MS-DRG 018 in previous years, when policies have supported greater patient access to CAR T-cell therapy. The proposed payment for CAR-T cases in FY 2027 would increase by 6.9%, demonstrating the agency's commitment to maintaining access to CAR T-cell therapies. The rule also continues differential reimbursement based on whether the treatment was provided as part of a clinical trial or an expanded access use case where hospitals do not incur a drug cost reflecting the variability in delivering care to patients with these therapies. We remain concerned about the long-term viability of MS-DRG 018 as more novel products enter the market. MS-DRG 018 currently has a wide variety of technologies with varying resource intensities assigned to it. If CMS were to assign new, higher volume, lower cost therapies to MS-DRG 018, it could potentially distort the relative weight of the MS-DRG and under-reimburse CAR T-cell therapies. **We share the agency's ongoing interest in developing a sustainable mechanism to accommodate the expanding portfolio of transformative therapies for which providers will need adequate reimbursement.**

Since CMS' FY 2022 policy that expanded MS-DRG 018 to include certain other immunotherapies, we have cautioned that the inclusion of additional procedure codes associated with other therapies could lead to reductions in the base rate for MS-DRG 018 over time and lead to under-reimbursement for CAR T-cell therapies.[iv] **We ask CMS to maintain the stability of the MS-DRG for CAR T-cell therapies by continuing to assess the appropriateness of therapies that may be assigned to MS-DRG 018. Specifically, CMS should ensure similarity of clinical use, treatment complexity, and resource utilization of a therapy for potential assignment to MS-DRG 018 including CAR T-cell therapies. Maintaining the integrity of MS-DRG 018 will ensure that the cost and resource needs of potential new additions to MS-DRG 018 do not harm access to current therapies.**

Low-Volume, High-Cost Rare Disease Treatments

In our FY 2023 IPPS comment letter, PMC applauded the agency for including a request for information calling attention to the special challenges of reimbursement adequacy often faced by low-volume, high-cost rare disease treatments when delivered in the hospital inpatient setting with MS-DRG reimbursement rates based on averages.[v] We were hopeful that CMS' request for information was an initial step toward addressing these challenges but it has been four years and the agency has yet to propose a solution in rulemaking. For each year since 2020, more than one third of all new personalized medicines approved by the U.S. Food and Drug Administration (FDA) have been to treat rare diseases, with a record 61 percent of new personalized medicines being approved to treat rare diseases in 2023.[vi], [vii] The increasing number of personalized medicines for rare diseases makes this a growing imperative for our community. **We continue to urge CMS to propose in rulemaking as soon as possible a meaningful solution for adequately reimbursing and reducing payment disparities for innovative rare disease treatments that can be critical to patients with few or no alternative treatment options.**

New Technology Add-on Payment (NTAP) Applications for Cell and Gene Therapies

New Technology Add-on Payments (NTAP)s encourage hospitals to adopt breakthrough technologies by helping them recover some of the increased costs associated with offering innovative treatments to patients. In our comments to CMS on previous IPPS proposed rules, PMC has asked CMS to grant NTAP status to new cell and gene therapies and consider how therapies in the research and development pipeline differ from 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. We understand that several applications for NTAP status included in the FY 2027 proposed rule relate to personalized medicine and may be at risk, including a cell-based autologous gene therapy for the treatment of WAS, an autologous cell sheet-based gene therapy for the treatment of RDEB, and an allogeneic stem cell and T-cell immunotherapy for treatment of acute myeloid leukemia, acute lymphoblastic leukemia, high-risk myelodysplastic syndrome, and mixed-phenotype acute leukemia. **We encourage CMS to assign NTAP status for Orca-T, Prademagene zamikeracel (ZEVASKYN™), Etuvetidigene autotemcel (WASKYRA™), and other new treatments and technologies supporting personalized medicine. Doing so will remove a potential barrier to patients accessing innovative treatments and tools advancing this approach to care.**

PMC thanks CMS for continuing a higher NTAP payment percentage for certain gene therapies treating sickle cell disease in FY 2027. PMC previously supported CMS' proposal in the FY 2025 proposed rule to increase the maximum NTAP payment percentage for these gene therapies to 75 percent.[viii] We shared CMS' concerns that the potential for hospitals to incur a significant financial loss due to insufficient new technology add-on payment could prevent hospitals from offering gene therapies for sickle cell disease to patients. This same concern, however, applies more broadly to all cell and gene therapies. There are over 700 cell and gene therapies in development,[ix] and these therapies present tremendous opportunities for patients who have historically had limited treatment options available to them. Similar to gene therapies for sickle cell disease, cell and gene therapies are often indicated for conditions that disproportionately affect patients with unmet medical needs and patients from underserved communities. By making long-lasting changes to the genetic make-up of patients' cells, cell and gene therapies can reverse the root causes of certain cancers and rare diseases with just one or a few treatments. These therapies often represent wholly new treatments for which there are no comparable, historical claims data under the IPPS. NTAP is needed to encourage hospitals to offer them to patients. Therefore, **we encourage CMS to extend eligibility for this higher NTAP payment to all novel cell and gene therapies.**

NTAP Framework and Proposed Policy Shift for Breakthrough Devices

NTAP is intended to address situations in which MS-DRG payment may be inadequate for cases involving a new technology. Under the traditional NTAP pathway, CMS requires applicants to demonstrate three elements including substantial clinical improvement (SCI) relative to existing technologies. Breakthrough devices involve years of development, significant investment, commitment of resources, running of clinical trials, and market launch preparations. The alternative pathway for breakthrough devices was intended to reduce the evidentiary burden for demonstrating SCI because breakthrough devices often face a longer timeline to achieve reimbursement, including coverage by Medicare and other payers.

PMC is concerned that the FY 2027 IPPS proposed rule would eliminate the fast-track NTAP alternative pathway for breakthrough device applications beginning in FY 2028. This alternative pathway has helped bridge the gap between FDA authorization and early hospital adoption of breakthrough devices, many intended for patients with life-threatening or life-altering conditions. Although the proposal would not eliminate NTAP altogether, it would remove a critical pathway providers rely on for securing additional Medicare reimbursement that enables them to provide patient access to new and innovative technologies.

Requiring breakthrough devices to meet the same criteria for NTAP status as non-breakthrough devices could have significant implications for the availability of innovative technologies for patients. Innovators will face less predictability around earlier inpatient utilization without the additional payment. Potential delays in clinical adoption for higher-cost technologies may also result from hospitals inability to absorb the expense without NTAP support. Therefore, **PMC urges CMS to reconsider the proposal to eliminate NTAP pathway for breakthrough devices.**

Conclusion

Thank you for your commitment to ensuring that beneficiaries have access to transformative technologies. We look forward to working with you and your colleagues at CMS to protect patient access to cell and gene therapies delivered in the hospital inpatient setting and to continue fostering innovation in personalized medicine 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

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[i] 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 Policy Changes and Fiscal Year 2027 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1849-P). April 14, 2026. https://www.govinfo.gov/content/pkg/FR-2026-04-14/pdf/2026-07203.pdf (Accessed June 4, 2026)

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[vii] Personalized Medicine Coalition. Personalized Medicine at FDA: The Scope and Significance of Progress in 2024. May 6, 2025. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2025/04/PMC_PM_at_FDA_2024.pdf. (Accessed June 4, 2026)

[viii] 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 June 4, 2026)

[ix] Lutzmayer, S & Wright, A. "Piping Hot: A Look at the State of Cell, Gene and RNA Therapies in Early 2023." IQVIA. May 2, 2023. https://www.iqvia.com/blogs/2023/04/piping-hot-a-look-at-the-state-of-cell-gene-and-rna-therapies-in-early2023. (Accessed June 4, 2026)